**UNITED STATES DISTRICT COURT**
**EASTERN DISTRICT OF TENNESSEE**
**AT GREENEVILLE**

| | | |
|---|---|---|
| **DAWN POYTHRESS and GARY POYTHRESS,** | ) | |
| **Plaintiffs,** | ) | |
| **vs.** | ) | **No.** |
| | ) | **Jury Trial Demanded** |
| **LiNA MEDICAL USA, INC., LiNA MEDICAL ApS, LiNA MEDICAL POLSKA SP. Z.O.O. and KEBOMED, AG,** | ) | |
| **Defendants.** | ) | |

# COMPLAINT

Come now the Plaintiffs, **Dawn Poythress and Gary Poythress,** and bring this civil action against the Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** and file a copy of this Complaint certified by their attorney as being true and correct for the purpose of accompanying the summons for compensatory damages in an amount no less than Six Million Five Hundred Twenty-Five Thousand Dollars ($6,525,000) and punitive damages no less than Two Million One Hundred Twenty-Five Thousand Dollars ($2,525,000) and in support thereof, alleges as follows:

## I. INTRODUCTION

1. This is a products liability, negligence and breach of warranty action against **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp.**

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**Z.o.o. and Kebomed, AG** resulting from the use of said Defendants' morcellator surgical products.

2. The Plaintiff, **Dawn Poythress,** underwent a laparoscopic-assisted supracervical hysterectomy (LASH) on April 6, 2015 at Morristown Hamblen Healthcare System in Morristown, Hamblen County, Tennessee.

## II. JURISDICTION AND VENUE

3. Pursuant to 28 U.S.C. §1332(a) the Court has jurisdiction over the parties and the subject matter of this cause of action. The matter in controversy, exclusive of cost of disbursements, exceeds the sum of Seventy-Five Thousand ($75,000.00) Dollars.

4. Venue in the Eastern District of Tennessee is proper under 28 U.S.C. §1391(b)(2) as a substantial part of the events or omissions giving rise to the claim occurred in this District.

## III. PARTIES

5. The Plaintiffs, **Dawn Poythress and Gary Poythress,** are citizens and residents of Hamblen County, Tennessee, residing at 4950 Stapleton Road, Morristown, Tennessee 37813.

6. The Defendant, **LiNA Medical USA, Inc.,** is a Georgia corporation who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically the LiNA Xcise Morcellator. The Defendant, **LiNA Medical USA, Inc.,** can be served

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through their registered agent: Philip Gilsdorf, 1856 Corporate Drive, Suite 135, Norcross, Georgia 30093.

7. The Defendant, **LiNA Medical ApS,** is a fictitious name, corporation or other entity organized and/or existing under the laws of Denmark who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically the LiNA Xcise Morcellator. The Defendant, **LiNA Medical ApS,** has a principal place of business at Formervangen 5, DK-2600 Glostrup, Denmark.

8. The Defendant, **LiNA Medical Polska Sp. Z.o.o.,** is a fictitious name, corporation or other entity organized and/or existing under the laws of Poland who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically the LiNA Xcise Morcellator. The Defendant, **LiNA Medical Polska Sp. Z.o.o.,** has a principal place of business at 62-080, Tarnowo Podgorne, 8A Rolna Str., Sady, Polska.

9. The Defendant, **Kebomed, AG,** is a fictitious name, corporation or other entity organized and/or existing under the laws of Switzerland who at all times material and relevant hereto was engaged in the business of manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or distributing minimally invasive gynecological surgical products, specifically the LiNA Xcise Morcellator. The

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Defendant, **Kebomed, AG,** has a principal place of business at D4 Platz 3, CH-6039 Root Längenbold, Switzerland.

10. The Defendant, **LiNA ApS,** continues to own and operate **Kebomed**, directly or indirectly. On that basis, and for the reasons given above, the Plaintiffs allege that Kebomed initially imported and distributed the LiNA Xcise Morcellator used in Ms. Poythress' surgery.

## IV. BACKGROUND AND FACTS

### Background of the Defendants

11. The Defendants designed the LiNA Xcise Laparoscopic Morcellator be used during laparoscopic gynecological and uterine surgery. In order to remove large or bulky tissue from the abdominal cavity through the laparoscopic ports, the tissue must be morcellated (cut up into very small pieces). This technique involves fragmenting the tissue such that it can pass through a small incision (i.e., the laparoscope port itself). The LiNA Xcise Laparoscopic Morcellator was designed to draw the tissue into a whirling blade, which then generates small (approximately 1 cm diameter) cores of the tissue, capable of being removed through the port incision. The velocity with which these blades spin causes dispersal of microscopic tumor fragments, thus seeding the peritoneum with small pieces of cancerous tissue. What is creased is a forced metastasis.

12. The LiNA Xcise Laparoscopic Morcellator was cleared by the Food and Drug Administration ("FDA") on or about March 2011. Such devices are required to undergo a "510(k)" process prior to being distributed, which simply requires the

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manufacturer to notify the FDA under section 510(k) of the Medical Device Amendments to the Food, Drug and Cosmetic Act of 1938 ("FDCA"), of its intent to market a device at least ninety (90) days prior to the device's introduction on the market, and to explain the device's "substantial equivalence" to a pre-FDA predicate device.

13. All Defendants promoted the LiNA Xcise as a novel device for patients undergoing laparoscopic uterine surgery.

14. Long before Plaintiff, **Dawn Poythress,** underwent surgery on April 6, 2015, Defendants knew or should have known that the LiNA Laparoscopic Power Morcellator (hereinafter referred to as "LPM") would cause occult malignant tissue fragments to be disseminated and implanted in the body, which in turn would upstage any cancer present and significantly worsen a woman's chance of survival. Although evidence was available to Defendants for decades prior to Plaintiff **Dawn Poythress'** surgery, Defendants failed to respond to multiple published studies and reports describing the risk of disseminating and upstaging occult cancer with LPM use, and failed to design, promote and otherwise make safe their LPM in a manner to reduce this life-threatening risk. Defendants knew or should have known that women requiring the use of their LPM devices were at a much higher risk of having cancer. Defendants knew or should have known that there were medical studies and other scientific research available stating that as many as one percent of hysterectomies turned out to have unknown or occult cancer.

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15. On information and belief, Defendants, as is industry practice, would routinely monitor the medical and lay media for articles on issues concerning their products, including LPMs.

16. On information and belief, there was ample literature collected by and known to the Defendants (or should have been known to the Defendants) at or before the time Plaintiff **Dawn Poythress** underwent her laparoscopic procedure which discussed and highlighted the risk of disseminating cancer when using the LPM. Defendants knew or should have known that their LPM would cause occult malignant tissue fragments to be disseminated and implanted in the body of women undergoing laparoscopic hysterectomies or myomectomies.

17. Defendants knew or should have known that for women undergoing laparoscopic hysterectomies or myomectomies for presumed fibroids, the risk of having a hidden deadly sarcoma was much higher than the 1 in 10,000 figure commonly provided to patients.

18. Defendants knew or should have known that women could not be adequately screened for malignancy prior to undergoing LPM surgery because certain types of cancers, including sarcomas, can mimic the radiographic appearance of benign uterine fibroids and do not always yield a positive biopsy result upon sampling. Therefore, there was no means of safely reducing the risk of disseminating cancer when undergoing surgery with an LPM.

19. Defendants knew or should have known that women undergoing surgery with LPM suffer worse long-term medical outcomes than women undergoing other

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available treatment options because of the cancer risks associated with the use of their devices.

20. Defendants knew or should have known that when malignant tissue undergoes Laparoscopic Power Morcellation, the resultant tissue specimens can delay diagnosis because the tissue's condition can prevent the pathologist from properly identifying and staging cancer, which can further worsen a patient's prognosis and treatment outcomes.

21. Indeed, morcellated specimens are poorly amenable to pathologic examination, because the morcellation abolishes many of the anatomic features that allow meaningful gross description, including the notions of orientation, dimension, adjacency, border, and margin.

20. As set forth herein, there were numerous journal articles and published studies available to the Defendants examining LPMs' potential to spread and worsen a woman's occult cancer. This evidence should have placed Defendants on notice that their LPMs were associated with and/or would cause the dissemination and upstaging of a woman's occult cancer.

21. On April 6, 2015, Plaintiff **Dawn Poythress** underwent uterine surgery; however, on April 17, 2014, the FDA issued a safety communication discouraging the use of laparoscopic power morcellation during hysterectomy or myomectomy surgical procedures for uterine fibroids. The FDA announced, "If laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis,

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significantly worsening the patient's likelihood of long-term survival." The FDA discouraged this practice because of this risk and the fact that "there is no reliable method for predicting whether a woman with fibroids may have a uterine sarcoma."

22. Based on the FDA safety communication, another manufacturer, Johnson & Johnson, suspended worldwide sales of their LPMs and later removed these devices altogether. Their reasoning was sound, if not overdue: "The risk-benefit assessment associated with the use of these devices in hysterectomy and myomectomy procedures for removing fibroids remains uncertain." The FDA further warned that based on an "FDA analysis of currently available data, it is estimated that **1 in 350 women undergoing hysterectomy or myomectomy for the treatment of fibroids is found to have an unsuspected uterine sarcoma**." *Id.* (emphasis added).

23. Significantly, in their "Quantitative Assessment of the Prevalence of Unsuspected Uterine Sarcoma in Women Undergoing Treatment of Uterine Fibroids," the FDA listed the studies upon which it relied in reaching its conclusions on the prevalence of unsuspected uterine sarcoma and uterine leiomyosarcoma.

24. The studies cited by the FDA were published in prominent medical journals between 1980 and 2014. Significantly, the majority of the studies cited by the FDA were available to Defendants **prior to the date on which Plaintiff Dawn Poythress underwent her surgery**.

25. On July 10 and 11, 2014, the FDA convened an Advisory Committee meeting of the Obstetrics and Gynecological Medical Device Advisory Committee on LPMs to discuss, among other topics, "whether a 'boxed warning' related to the risk of

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cancer spread should be required for Laparoscopic Power Morcellators."

26. On November 24, 2014, the FDA updated its prior safety communication regarding power morcellators. Rather than merely discouraging power morcellation in the treatment of uterine fibroids, the FDA warned against "the use of Laparoscopic Power Morcellators in the majority of women undergoing myomectomy or hysterectomy for treatment of fibroids."

27. In its warning, the FDA stated, "[I]f laparoscopic power morcellation is performed in women with unsuspected uterine sarcoma, there is a risk that the procedure will spread the cancerous tissue within the abdomen and pelvis, significantly worsening the patient's long-term survival." According to the Safety Communication, the FDA, in an unprecedented move, was issuing an "Immediately In Effect" guidance that asked manufacturers of LPMs to include two contraindications and a boxed warning in their product labeling, which warned the medical community against using LPMs in the majority of women undergoing myomectomy or hysterectomy, and recommended that doctors share this information with their patients.

28. Upon information and belief, this is the first time the FDA has used its "Immediately In Effect" authority to warn the public about a product.

29. A boxed warning is the strongest warning the FDA implements for medical devices.

30. As part of the warning, the FDA recommended that manufacturers of LPMs prominently include the following contraindications and boxed warning in their

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product labeling:

> ***CONTRAINDICATION:*** ***Laparoscopic Power Morcellators are contraindicated in gynecologic surgery in which the tissue to be morcellated is known or suspected to contain malignancy.***
>
> ***CONTRAINDICATION:*** ***Laparoscopic Power Morcellators are contraindicated for removal of uterine tissue containing suspected fibroids in patients who are:***
>
> - *Peri- or post-menopausal, or*
> - *Candidates for en bloc tissue removal, for example, through the vagina or via a mini-laparotomy incision.*
>
> ***WARNING:*** **Uterine tissue may contain unsuspected cancer. The use of Laparoscopic Power Morcellators during fibroid surgery may spread cancer, and decrease the long-term survival of patients. This information should be shared with patients when considering surgery with the use of these devices.**

31. In an August 7, 2015 letter, legislators asked the United States Government Accountability Office (GAO) to "investigate the root cause failure that ultimately led to the FDA's black box warning on the use of Laparoscopic Power Morcellators in November 2014 – over two decades after it was first approved."

32. On September 4, 2015, the GAO announced it would investigate the controversy stemming from wide use of power morcellators known to spread unsuspected cancers during hysterectomies and myomectomies.

33. Notwithstanding that the Defendants, and each of them, had actual knowledge and constructive notice, or in the exercise of reasonable care, should have known of the risks of disseminating, seeding and upstaging cancer by the use of their LPM, the Defendants, and each of them, failed to adequately warn physicians and/or patients, including Plaintiff **Dawn Poythress** and her physicians, of the risks.

34. LPMs are not necessary for the treatment of uterine fibroids. Safer, more

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reasonable and feasible alternative methods for treating uterine fibroids that do not employ the use of an LPM exist and have existed for decades. For example, other surgical methods have long been widely used, and are still used, for the safe removal of the uterus and uterine fibroids including, but not limited to, vaginal hysterectomies and abdominal hysterectomies whereby the uterus can be removed intact rather than being fragmented by an LPM in such a way that cancer cells are disseminated, seeded and spread throughout the abdomen.

35. Prior to and at the time of designing, manufacturing, marketing, promoting and selling the LiNA LPM, the Defendants, and each of them, had actual knowledge and constructive notice, or in the exercise of reasonable care, should have known that they were producing defective devices capable of disseminating, seeding and upstaging malignancies when used as designed and intended for the treatment of uterine fibroids. Prior to and at the time of designing, manufacturing, marketing, promoting and selling of the LiNA LPM, the Defendants, and each of them, had actual knowledge and constructive notice or in the exercise of reasonable care, should have known that they were producing defective medical devices that were killing and/or injuring patients.

36. Prior to and at the time of designing, manufacturing, marketing, promoting and selling of the LiNA LPM, the Defendants, and each of them, had actual knowledge and constructive notice or in the exercise of reasonable care, should have known that the incidence of undiagnosed uterine cancers in patients requiring fibroid surgery far exceeded what the Defendants were representing. Despite the foregoing,

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the Defendants, and each of them, continued to act with reckless and/or intentional disregard for the safety of patients and continued to manufacture, sell and promote LINA LPMs, knowing that they could and did cause catastrophic injuries and death.

37. The LiNA LPM is unreasonably dangerous and/or defective because, as in the case of Plaintiff **Dawn Poythress**, it can disseminate, seed and upstage an undiagnosed and unsuspected uterine cancer leading to devastating metastatic cancer and eventual death.

**Dawn Poythress' Use of the LiNA Xcise Laparoscopic Morcellator And Resulting Injuries**

38. On April 6, 2015, the Plaintiff, **Dawn Poythress,** underwent a laparoscopic-assisted supracervical hysterectomy (LASH) with uterine morcellation by Peter Clark, M.D. at Morristown Hamblen Healthcare System due to menorrhagia, severe dysmenorrhea, pelvic pain and dyspareunia.

39. In cutting, shredding and fragmenting the uterus and fibroids while still within Ms. Poythress, the LPM disseminated and seeded cancer throughout her abdominal cavity and spreading her cancer, worsening her long-term prognosis and the natural course of her cancer.

40. As a result of Defendants' claims regarding the effectiveness, safety and benefits of the LMP, Plaintiff and her physicians were unaware that Plaintiff would be exposed to the risk of disseminating occult cancerous tissue.

41. Due to the nature of Plaintiff **Dawn Poythress'** endometrioid adenocarcinoma with squamous differentiation, she will face a lengthy course of serial

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imaging studies and treatment in order to monitor and address her cancer or potential cancer.

42. The Plaintiff followed up with her OB/GYN at her post-op appointment on April 17, 2015, when he advised her of the endometrioid adenocarcinoma at which time her OB/GYN advised her to follow-up on a regular basis, but didn't feel that any other surgery was necessary.

43. The Plaintiff, **Dawn Poythress,** took the precaution of making an appointment with a gynecologist/oncologist, Larry Kilgore, M.D., at the University of Tennessee Medical Center and saw Dr. Kilgore on April 28, 2015 at which Dr. Kilgore concurred with her previous doctor to follow-up on a regular basis until he learned that a power morcellator had been used during her surgery on April 6, 2015. It was at this appointment that the Plaintiff first learned of an issue with LPM.

44. Upon learning that a power morcellator had been used during the Plaintiff's laparoscopic-assisted supracervical hysterectomy (LASH) on April 6, 2015, Dr. Kilgore immediately changed his treatment plan and recommended that the Plaintiff undergo a Robotic assisted trachelectomy with pelvic lymphadenectomy on May 15, 2015 at the University of Tennessee Medical Center.

45. The Plaintiff now has other suspicious spots for cancer in her pelvic region for which the diagnosis is currently unknown.

46. The Plaintiff, **Dawn Poythress**, brings this civil action against the Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** for personal injuries and damages, medical bills and

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expenses which she was caused to receive.

47. The Plaintiff, **Gary Poythress,** brings this civil action against the Defendants for loss of consortium, which he was caused to receive as a result of his wife's injuries.

48. The Plaintiff, **Dawn Poythress**, brings this civil action against the Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** for injuries which she was caused to receive. As a result of this accident, **Dawn Poythress** has sustained serious and disabling injuries. Said injuries to the Plaintiff have resulted in permanent disability and have impaired her capacity for work, labor, business and the enjoyments and pleasures of life. As a result of these injuries, Plaintiff has incurred and shall continue to incur medical bills as well as pain and suffering.

49. It is alleged that each and every Defendant herein failed to warn about the possibility of seeding and undiagnosed sarcoma throughout the peritoneal cavity when using the Defendants' power morcellator for the procedure.

50. The Defendants were each aware of the risks, complications and/or adverse events associated with their products used for uterine morcellation.

## V. COUNT I – NEGLIGENCE

51. The Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** owed a duty to manufacture, compound, label, market, distribute and supply and/or sell products, including minimally invasive gynecologic products, including products used for uterine

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morcellation in such a way as to avoid harm to persons upon whom they are used, such as the Plaintiff herein, or to refrain from such activities following knowledge and/or constructive knowledge that such product is harmful to persons upon whom it is used.

52. The Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** owed a duty to warn of the hazards and dangers associated with the use of its products, specifically minimally invasive gynecologic products, including products used for uterine morcellation, for patients such as the Plaintiff herein, so as to avoid harm.

53. The Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG**, acting by and through their authorized divisions, subsidiaries, agents, servants, and employees, were guilty of carelessness, recklessness, negligence, willful, wanton and reckless disregard for human life and safety in manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce, minimally invasive gynecologic products, including products used for uterine morcellation, both generally, and in the following particular respects:

a. Failing to conduct adequate and appropriate testing of minimally invasive gynecologic products, specifically including, but not limited to, products fused for uterine morcellation;

b. Putting products used for uterine morcellation on the market without first conducting adequate testing to determine possible side effects;

c. Putting products used for uterine morcellation on the market without adequate testing of its dangers to humans;

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d. Failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, which testing evidenced such products potential harm to humans;

e. Failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, which indicated such products potential harm to humans;

f. Failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

g. Failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation;

h. Failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

i. Failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

j. Concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation are harmful to humans;

k. Promoting, marketing, advertising and/or selling products used for uterine morcellation for use on patients given their knowledge and experience of such products' potential harmful effects;

l. Failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

m. Failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products

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engaged in the manufacture of said products, specifically including products used for uterine morcellation;

n. Placing and/or permitting the placement of the products used for uterine morcellation, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

o. Failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation to be harmful to humans;

p. Failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients;

q. Disregarding the safety of users and consumers of products used for uterine morcellations, including Plaintiff herein, under the circumstances by failing to adequately warn of said products' potential harm to humans;

r. Disregarding the safety of users and consumers of the products used for uterine morcellation, including Plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by filing to withdraw said products from the market and/or restrict their usage;

s. Disregarding publicity, government and/or industry studies, information, documentation and recommendations, consider complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

t. Failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

u. Failing to remove products used for uterine morcellations from the stream of commerce;

v. Failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

w. Failing to use due care under the circumstances;

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x. Such other acts or omissions constituting negligence and carelessness as may appear during the course of discovery or at the trial of this matter;

y. Promoting the products used for uterine morcellation as safe and/or safer than other comparative methods of lesion removal;

z. Promoting the products used for uterine morcellation on websites aimed at creating user and consumer demand; and,

aa. Failing to conduct and/or respond to post-marketing surveillance of complications and injuries.

**COUNT II – STRICT PRODUCTS LIABILITY**

54. As a result of the unreasonably dangerous and defective condition of the products used for uterine morcellation which the Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into the stream of commerce, they are strictly liable to the Plaintiffs, **Dawn Poythress and Gary Poythress,** pursuant to T.C.A. § 29-28-101 *et. seq.* for their injuries and/or losses, which they directly and proximately caused, based on the following:

a. Failing to properly and adequately design the products used for uterine morcellation;

b. Failing to properly and adequately manufacture the products used for uterine morcellation;

c. Such other defects as shall be revealed in the course of discovery;

d. Failing to conduct adequate and appropriate testing of minimally invasive gynecologic products, specifically including, but not limited to, products fused for uterine morcellation;

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e. Putting products used for uterine morcellation on the market without first conducting adequate testing to determine possible side effects;

f. Putting products used for uterine morcellation on the market without adequate testing of its dangers to humans;

g. Failing to recognize the significance of their own and other testing of, and information regarding, products used for uterine morcellation, which testing evidenced such products potential harm to humans;

h. Failing to respond promptly and appropriately to their own and other testing of, and information regarding products used for uterine morcellation, which indicated such products potential harm to humans;

i. Failing to promptly and adequately warn of the potential of the products used for uterine morcellation to be harmful to humans;

j. Failing to promptly and adequately warn of the potential for the metastases of cancer when using products used for uterine morcellation;

k. Failing to promptly, adequately, and appropriately recommend testing and monitoring of patients upon whom products used for uterine morcellation in light of such products potential harm to humans;

l. Failing to properly, appropriately, and adequately monitor the post-market performance of products used for uterine morcellation and such products effects on patients;

m. Concealing from the FDA, National Institutes of Health, the general medical community and/or physicians, their full knowledge and experience regarding the potential that products used for uterine morcellation are harmful to humans;

n. Promoting, marketing, advertising and/or selling products used for uterine morcellation for use on patients given their knowledge and experience of such products' potential harmful effects;

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o. Failing to withdraw products used for uterine morcellation from the market, restrict its use and/or warn of such products' potential dangers, given their knowledge of the potential for its harm to humans;

p. Failing to fulfill the standard of care required of a reasonable, prudent, minimally invasive gynecological surgical products engaged in the manufacture of said products, specifically including products used for uterine morcellation;

q. Placing and/or permitting the placement of the products used for uterine morcellation, into the stream of commerce without warnings of the potential for said products to be harmful to humans and/or without properly warning of said products' dangerousness;

r. Failing to disclose to the medical community in an appropriate and timely manner, facts relative to the potential of the products used for uterine morcellation to be harmful to humans;

s. Failing to respond or react promptly and appropriately to reports of products used for uterine morcellation causing harm to patients;

t. Disregarding the safety of users and consumers of products used for uterine morcellations, including Plaintiff herein, under the circumstances by failing to adequately warn of said products' potential harm to humans;

u. Disregarding the safety of users and consumers of the products used for uterine morcellation, including Plaintiff herein, and/or her physicians' and/or hospital, under the circumstances by filing to withdraw said products from the market and/or restrict their usage;

v. Disregarding publicity, government and/or industry studies, information, documentation and recommendations, consider complaints and reports and/or other information regarding the hazards of the products used for uterine morcellation and their potential harm to humans;

w. Failing to exercise reasonable care in informing physicians and/or hospitals using the products used for uterine morcellation about their own knowledge regarding said products' potential harm to humans;

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ATTORNEYS AT LAW
918 WEST FIRST NORTH STREET
POST OFFICE BOX 724
MORRISTOWN, TENNESSEE
37815-0724

x. Failing to remove products used for uterine morcellations from the stream of commerce;

y. Failing to test products used for uterine morcellation properly and/or adequately so as to determine its safety for use;

55. In addition, the aforesaid incident and Plaintiffs' injuries and losses were the direct and proximate result of the Defendants' manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or placing into the stream of commerce the products used for uterine morcellation, without proper and adequate warnings regarding the potential said products' harm to humans and as otherwise set forth when said Defendants knew or should have known of the need for such warnings and/or recommendations.

**COUNT III – BREACH OF WARRANTY**

56. Plaintiffs incorporate all allegations listed in paragraphs number 5 through 23 herein.

57. In the advertising and marketing of the products used for uterine morcellation, which was directed to physicians, hospitals and consumers, the Defendants warranted that said product or products were safe for the use which had the natural tendency to induce physicians and hospitals to use the same for patients and for patients to want to be treated with the same.

58. The aforesaid warranties were breached by Defendants in that the products used for uterine morcellation constituted a serious danger to the user.

59. As a direct and proximate result of Defendants' breach of express warranty, Plaintiffs suffered serious injuries and financial losses and harm.

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60. At all relevant and material times, Defendants manufactured, distributed, advertised, promoted and sold the foregoing products used for uterine morcellation.

61. At all relevant times, Defendants intended that the products used for uterine morcellation be used in the manner that the Plaintiff's physician, in fact, used it and Defendants implied warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

62. Defendants breached various implied warranties with respect to the products used for uterine morcellation, including:

a. Defendants represented through their labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the products used for uterine morcellations were safe, and withheld and concealed information about the substantial risks of serious injury and/or death associated with using the products used for uterine morcellation;

b. Defendants represented that the products used for uterine morcellation were as safe and/or safer than other alternative surgical approaches that did not include the use of the said products, and concealed information which demonstrated that said products were not safer than alternatives available on the market; and

c. Defendants represented that the products used for uterine morcellation were more efficacious than other alternative surgical approaches and techniques and concealed information, regarding the true efficacy of said products.

63. In reliance upon Defendants' implied warranty, Plaintiff's physician used said products as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed and marketed by the Defendants.

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64. Defendants breached their implied warranty to Plaintiff in that said products used for uterine morcellation were not of merchantable quality, safe and fit for their intended use in T.C.A § 47-2-313, T.C.A § 47-2-314, and T.C.A § 47-2-315.

65. As a direct and proximate consequence of Defendant's breach of implied warranty and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, the Plaintiffs sustained injuries and damages alleged herein including pain and suffering.

66. As a further direct and proximate result of the acts of the Defendants, Plaintiffs suffered emotional distress and loss of consortium.

67. The aforementioned acts of the Defendants were reckless and intentional and as such the Defendants should be held liable for punitive damages.

**WHEREFORE**, the Plaintiffs, **Dawn Poythress and Gary Poythress,** ask for judgment against the Defendants, **LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG,** for compensatory damages in an amount no less than Six Million Five Hundred Twenty-Five Thousand Dollars ($6,525,000) and punitive damages no less than Two Million One Hundred Twenty-Five Thousand Dollars ($2,525,000) and ask for a jury in the trial of this cause.

Respectfully submitted,

*/s/ F. Braxton Terry*
F. Braxton Terry, BPR #018248

THE TERRY LAW FIRM
ATTORNEYS AT LAW
918 WEST FIRST NORTH STREET
POST OFFICE BOX 724
MORRISTOWN, TENNESSEE
37815-0724

Of Counsel:

THE TERRY LAW FIRM
918 West First North Street
P.O. Box 724
Morristown, TN 37815
423-586-5800

**CERTIFICATE OF SERVICE**

I hereby certify that on April 27, 2016 a copy of the foregoing document was filed electronically. Notice of this filing will be sent by operation of the Court's electronic filing system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail. Parties may access this filing through the Court's electronic filing system.

*/s/ F. Braxton Terry*
F. Braxton Terry

THE TERRY LAW FIRM
ATTORNEYS AT LAW
918 WEST FIRST NORTH STREET
POST OFFICE BOX 724
MORRISTOWN, TENNESSEE
37815-0724

JS 44 (Rev. 11/15)

# CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. *(SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM.)*

**I. (a) PLAINTIFFS**
Dawn Poythress and Gary Poythress

(b) County of Residence of First Listed Plaintiff Hamblen
*(EXCEPT IN U.S. PLAINTIFF CASES)*

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
F. Braxton Terry, The Terry Law Firm, P.O. Box 724
Morristown, TN 37815, 423-586-5800

**DEFENDANTS**
LiNA Medical USA, Inc., LiNA Medical ApS, LiNA Medical Polska Sp. Z.o.o. and Kebomed, AG

County of Residence of First Listed Defendant
*(IN U.S. PLAINTIFF CASES ONLY)*
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

Attorneys *(If Known)*

**II. BASIS OF JURISDICTION** *(Place an "X" in One Box Only)*

- ☐ 1 U.S. Government Plaintiff
- ☐ 3 Federal Question *(U.S. Government Not a Party)*
- ☐ 2 U.S. Government Defendant
- ☒ 4 Diversity *(Indicate Citizenship of Parties in Item III)*

**III. CITIZENSHIP OF PRINCIPAL PARTIES** *(Place an "X" in One Box for Plaintiff and One Box for Defendant)*
*(For Diversity Cases Only)*

| | PTF | DEF | | PTF | DEF |
|---|---|---|---|---|---|
| Citizen of This State | ☒ 1 | ☐ 1 | Incorporated *or* Principal Place of Business In This State | ☐ 4 | ☐ 4 |
| Citizen of Another State | ☐ 2 | ☐ 2 | Incorporated *and* Principal Place of Business In Another State | ☐ 5 | ☒ 5 |
| Citizen or Subject of a Foreign Country | ☐ 3 | ☐ 3 | Foreign Nation | ☐ 6 | ☐ 6 |

**IV. NATURE OF SUIT** *(Place an "X" in One Box Only)*

| CONTRACT | TORTS | | FORFEITURE/PENALTY | BANKRUPTCY | OTHER STATUTES |
|---|---|---|---|---|---|
| ☐ 110 Insurance | PERSONAL INJURY | PERSONAL INJURY | ☐ 625 Drug Related Seizure of Property 21 USC 881 | ☐ 422 Appeal 28 USC 158 | ☐ 375 False Claims Act |
| ☐ 120 Marine | ☐ 310 Airplane | ☐ 365 Personal Injury - Product Liability | ☐ 690 Other | ☐ 423 Withdrawal 28 USC 157 | ☐ 376 Qui Tam (31 USC 3729(a)) |
| ☐ 130 Miller Act | ☐ 315 Airplane Product Liability | ☒ 367 Health Care/ Pharmaceutical Personal Injury Product Liability | | PROPERTY RIGHTS | ☐ 400 State Reapportionment |
| ☐ 140 Negotiable Instrument | ☐ 320 Assault, Libel & Slander | ☐ 368 Asbestos Personal Injury Product Liability | | ☐ 820 Copyrights | ☐ 410 Antitrust |
| ☐ 150 Recovery of Overpayment & Enforcement of Judgment | ☐ 330 Federal Employers' Liability | PERSONAL PROPERTY | | ☐ 830 Patent | ☐ 430 Banks and Banking |
| ☐ 151 Medicare Act | ☐ 340 Marine | ☐ 370 Other Fraud | | ☐ 840 Trademark | ☐ 450 Commerce |
| ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans) | ☐ 345 Marine Product Liability | ☐ 371 Truth in Lending | LABOR | SOCIAL SECURITY | ☐ 460 Deportation |
| ☐ 153 Recovery of Overpayment of Veteran's Benefits | ☐ 350 Motor Vehicle | ☐ 380 Other Personal Property Damage | ☐ 710 Fair Labor Standards Act | ☐ 861 HIA (1395ff) | ☐ 470 Racketeer Influenced and Corrupt Organizations |
| ☐ 160 Stockholders' Suits | ☐ 355 Motor Vehicle Product Liability | ☐ 385 Property Damage Product Liability | ☐ 720 Labor/Management Relations | ☐ 862 Black Lung (923) | ☐ 480 Consumer Credit |
| ☐ 190 Other Contract | ☐ 360 Other Personal Injury | | ☐ 740 Railway Labor Act | ☐ 863 DIWC/DIWW (405(g)) | ☐ 490 Cable/Sat TV |
| ☐ 195 Contract Product Liability | ☐ 362 Personal Injury - Medical Malpractice | | ☐ 751 Family and Medical Leave Act | ☐ 864 SSID Title XVI | ☐ 850 Securities/Commodities/ Exchange |
| ☐ 196 Franchise | | | ☐ 790 Other Labor Litigation | ☐ 865 RSI (405(g)) | ☐ 890 Other Statutory Actions |
| | | | ☐ 791 Employee Retirement Income Security Act | | ☐ 891 Agricultural Acts |
| REAL PROPERTY | CIVIL RIGHTS | PRISONER PETITIONS | | FEDERAL TAX SUITS | ☐ 893 Environmental Matters |
| ☐ 210 Land Condemnation | ☐ 440 Other Civil Rights | Habeas Corpus: | IMMIGRATION | ☐ 870 Taxes (U.S. Plaintiff or Defendant) | ☐ 895 Freedom of Information Act |
| ☐ 220 Foreclosure | ☐ 441 Voting | ☐ 463 Alien Detainee | ☐ 462 Naturalization Application | ☐ 871 IRS—Third Party 26 USC 7609 | ☐ 896 Arbitration |
| ☐ 230 Rent Lease & Ejectment | ☐ 442 Employment | ☐ 510 Motions to Vacate Sentence | ☐ 465 Other Immigration Actions | | ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision |
| ☐ 240 Torts to Land | ☐ 443 Housing/ Accommodations | ☐ 530 General | | | ☐ 950 Constitutionality of State Statutes |
| ☐ 245 Tort Product Liability | ☐ 445 Amer. w/Disabilities - Employment | ☐ 535 Death Penalty | | | |
| ☐ 290 All Other Real Property | ☐ 446 Amer. w/Disabilities - Other | Other: | | | |
| | ☐ 448 Education | ☐ 540 Mandamus & Other | | | |
| | | ☐ 550 Civil Rights | | | |
| | | ☐ 555 Prison Condition | | | |
| | | ☐ 560 Civil Detainee - Conditions of Confinement | | | |

**V. ORIGIN** *(Place an "X" in One Box Only)*

☒ 1 Original Proceeding ☐ 2 Removed from State Court ☐ 3 Remanded from Appellate Court ☐ 4 Reinstated or Reopened ☐ 5 Transferred from Another District *(specify)* ☐ 6 Multidistrict Litigation

**VI. CAUSE OF ACTION**
Cite the U.S. Civil Statute under which you are filing *(Do not cite jurisdictional statutes unless diversity)*:
28 USC § 1332
Brief description of cause:
products liability

**VII. REQUESTED IN COMPLAINT:**
☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P
DEMAND $ 2,525.00
CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

**VIII. RELATED CASE(S) IF ANY** *(See instructions)*:
JUDGE _____ DOCKET NUMBER _____

DATE 04/27/2016
SIGNATURE OF ATTORNEY OF RECORD F. Braxton Terry

**FOR OFFICE USE ONLY**

RECEIPT # _____ AMOUNT _____ APPLYING IFP _____ JUDGE _____ MAG JUDGE _____

# UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

| | | |
|---|---|---|
| Dawn Poythress and Gary Poythress<br><br>*Plaintiff(s)*<br>v.<br><br>LiNA Medical USA, Inc.<br>LiNA Medical ApS<br>LiNA Medical Polska Sp. Z.o.o.<br>and Kebomed, AG<br>*Defendant(s)* | ) | Civil Action No. |

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)* LiNA Medical USA, Inc.
Philip Gilsdorf
1856 Corporate Drive, Suite 135
Norcross, GA 30093

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: F. Braxton Terry
The Terry Law Firm
P.O. Box 724
Morristown, TN 37815

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

❒ I personally served the summons on the individual at *(place)* _____

_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

# UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

| | | |
|---|---|---|
| Dawn Poythress and Gary Poythress<br>*Plaintiff(s)* | ) | |
| v. | ) | Civil Action No. |
| LiNA Medical USA, Inc.<br>LiNA Medical ApS<br>LiNA Medical Polska Sp. Z.o.o.<br>and Kebomed, AG<br>*Defendant(s)* | ) | |

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LiNA Medical ApS
Formervangen 5
DK-2600 Glostrup
Denmark

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: F. Braxton Terry
The Terry Law Firm
P.O. Box 724
Morristown, TN 37815

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____

was received by me on *(date)* _____.

❒ I personally served the summons on the individual at *(place)* _____

on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

# UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

Dawn Poythress and Gary Poythress

*Plaintiff(s)*

v.

LiNA Medical USA, Inc.
LiNA Medical ApS
LiNA Medical Polska Sp. Z.o.o.
and Kebomed, AG

*Defendant(s)*

Civil Action No.

## SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)* LiNA Medical Polska Sp. Z.o.o.
62-080
Tarnowo Podgome
8A Rolna Str
Sady, Polska

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: F. Braxton Terry
The Terry Law Firm
P.O. Box 724
Morristown, TN 37815

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____.

☐ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

☐ I left the summons at the individual's residence or usual place of abode with *(name)* _____, a person of suitable age and discretion who resides there, on *(date)* _____, and mailed a copy to the individual's last known address; or

☐ I served the summons on *(name of individual)* _____, who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

☐ I returned the summons unexecuted because _____ ; or

☐ Other *(specify)*:

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

*Server's signature*

_____

*Printed name and title*

_____

*Server's address*

Additional information regarding attempted service, etc:

# UNITED STATES DISTRICT COURT

for the

Eastern District of Tennessee

| | | |
|---|---|---|
| Dawn Poythress and Gary Poythress<br><br>*Plaintiff(s)*<br>v.<br><br>LiNA Medical USA, Inc.<br>LiNA Medical ApS<br>LiNA Medical Polska Sp. Z.o.o.<br>and Kebomed, AG<br>*Defendant(s)* | ) | Civil Action No. |

**SUMMONS IN A CIVIL ACTION**

To: *(Defendant's name and address)* Kebomed AG
D4 Platz 3
CH-6039
Root Längenbold, Switzerland

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are: F. Braxton Terry
The Terry Law Firm
P.O. Box 724
Morristown, TN 37815

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

*CLERK OF COURT*

Date: _____

_____
*Signature of Clerk or Deputy Clerk*

Civil Action No.

**PROOF OF SERVICE**

***(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))***

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_____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____

_____, a person of suitable age and discretion who resides there,

on *(date)* _____, and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____, who is

designated by law to accept service of process on behalf of *(name of organization)* _____

_____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
*Server's signature*

_____
*Printed name and title*

_____
*Server's address*

Additional information regarding attempted service, etc: