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9 Attorneys for Plaintiffs
10 LISA NIELSEN and KURT NIELSEN

11 UNITED STATES DISTRICT COURT
12 EASTERN DISTRICT OF CALIFORNIA

13 LISA NIELSEN, and KURT NIELSEN

Case No.:

14 Plaintiffs,

COMPLAINT FOR:

15 v.

1. **NEGLIGENCE**
2. **STRICT PRODUCTS LIABILITY**
3. **BREACH OF EXPRESS WARRANTY**
4. **BREACH OF IMPLIED WARRANTY**
5. **FRAUD**
6. **LOSS OF SERVICES**

16 GYRUS ACMI, LP, a Minnesota Limited
17 Partnership; GYRUS ACMI, LLC, a
18 Minnesota Limited Liability Company;
19 and DOES 1-50,

20 Defendants.

JURY TRIAL IS REQUESTED

21 Plaintiffs LISA NIELSEN and KURT NIELSEN, complaining of the defendants and
22 seeking a trial by jury of their claims, allege as follows:

23 **I. INTRODUCTION**

24 1. This action is being brought for injuries and damages caused to plaintiffs from the
25 use of a product known as a power morcellator in connection with a hysterectomy on plaintiff
26 LISA NIELSEN that was manufactured, sold and distributed by GYRUS ACMI, LP, GYRUS
27 ACMI, LLC and as Does 1 though 50.

28 2. Plaintiff LISA NIELSEN had a surgical procedure known as a hysterectomy
("uterine morcellation") assisted by the use of a GYRUS ACMI, LP bipolar morcellator ("Gyrus
Power Morcellator").

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1 mentioned, each of the defendants, whether specifically named or designated in this Complaint
2 as a DOE defendant, was the agent, representative, joint-venture, co-conspirator, consultant,
3 predecessor, successor, servant, or employee of each of the remaining defendants, and in doing
4 the acts alleged herein, was acting in the course and scope of such agency, representation, joint
5 venture, conspiracy, consultancy, predecessor agreement, successor agreement, service and
6 employment with knowledge, acquiescence and ratification of each and every remaining
7 defendant.

8 10. Defendants DOES 1 through 50, inclusive, were engaged in the business of
9 manufacturing and/or selling and/or supplying and/or marketing and/or designing and/or
10 distributing minimally invasive gynecological surgical products, specifically, the product(s) used
11 upon Plaintiff LISA NIELSEN.

12 IV. BACKGROUND AND FACTS

13 11. Paragraphs 1 through 10 are incorporated by this reference into this cause of
14 action as if they were set forth in full.

15 12. Plaintiff LISA NIELSEN underwent a surgical procedure known as a
16 hysterectomy during which surgery the Gyrus Power Morcellator was used. This surgery took
17 place in the city of Carmichael, California.

18 13. Prior to plaintiff LISA NIELSEN's surgery, she was unaware that she had
19 cancer.

20 14. More than a year after the procedure, Plaintiff found out that she had seven
21 cancerous in her abdomen. She thereafter underwent additional surgeries and chemotherapy, and
22 continues to be actively monitored for new tumors.

23 15. Within the last two years, Plaintiff LISA NIELSEN learned that the tumors in her
24 abdominal existed because the Gyrus Power Morcellator had been used during her hysterectomy.
25 That surgery disseminated the cancer cells that were in her uterine fibroids, and that such
26 dissemination could lead to metastatic disease at more locations.

27 16. Plaintiff LISA NIELSEN was never warned prior to her hysterectomy that there
28

1 was any chance that the “fibroids” could be cancerous, nor that using the Gyrus Power
2 Morcellator in the hysterectomy brought any chance of spreading cancer.

3 17. It is alleged that each and every defendant herein failed to warn that the use of the
4 Gyrus Power Morcellator increased the possibility of dissemination of cancer throughout
5 Plaintiff’s body.

6 18. Defendants knew or should have known of the risks, complications, and/or
7 adverse events associated with their products used for uterine morcellation, but continued to sell
8 them without disclosing the risk involved with the use of their products.

9
10 **FIRST CAUSE OF ACTION**

11 **NEGLEGENGE**

12 19. Plaintiff incorporates paragraphs 1 to 18 herein by this reference.

13 20. Defendants GYRUS ACMI, LP, GYRUS ACMI, LLC and Does 1 through 50,
14 inclusive, (hereafter collectively referred to as “Defendants”), owed a duty to design,
15 manufacture, label, market, distribute, and supply and/or sell a product like the Gyrus Power
16 Morcellator in such a way as to avoid harm to persons upon whom it was used, including
17 plaintiff LISA NIELSEN, or to refrain from such activities following knowledge and/or
18 constructive knowledge that such product is harmful to persons upon whom it is used.

19 21. Defendants owed a duty to warn of the hazards and dangers associated with the
20 use of its product the Gyrus Power Morcellator and its associated minimally invasive
21 gynecological products, for patients such as plaintiff herein, so as to avoid harm.

22 22. Defendants, acting by and through their authorized divisions, subsidiaries, agents,
23 servants, and employees, were guilty of carelessness, recklessness, negligence, gross negligence,
24 and willful, wanton, outrageous and reckless disregard for human life and safety in
25 manufacturing, designing, labeling, marketing, distributing, supplying and/or selling and/or
26 placing into the stream of commerce, minimally invasive gynecological products, including the
27 Gyrus Power Morcellator, both generally, and in the following respects:

28 a. failing to conduct adequate and appropriate testing of minimally invasive

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1 gynecological products, specifically including, but not limited to, products used for uterine
2 morcellation;

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

5 c. putting products used for uterine morcellation on the market without
6 adequate testing of its dangers to humans

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

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

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

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

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

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

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

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

28 l. failing to withdraw products used for uterine morcellation from the

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1 market, restrict its use and/or warn of such products' potential dangers, given their knowledge of
2 the potential for its harm to humans;

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

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

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

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

14 q. disregarding the safety of users and consumers of products used for
15 uterine morcellation, including plaintiff herein, under the circumstances by failing to adequately
16 warn of said products' potential harm to humans;

17 r. disregarding the safety and users and consumers of the products used for
18 uterine morcellation, including plaintiff herein, and/or her physicians and/or hospital, under the
19 circumstances by failing to withdraw said products from the market and/or restrict their usage;

20 s. disregarding publicity, government and/or industry studies, information,
21 documentation and recommendations, consumer complaints and reports and/or other information
22 regarding the hazards of the products used for uterine morcellation and their potential harm to
23 humans;

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

27 u. failing to remove products used for uterine morcellation from the stream
28 of commerce;

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

3 w. promoting the products used for uterine morcellation as safe and/or safer
4 than other comparative methods of lesion removal;

5 x. promoting the products used for uterine morcellation on websites aimed at
6 creating user and consumer demand;

7 y. failing to conduct and/or respond to post-marketing surveillance of
8 complications and injuries.

9 z. failing to use due care under the circumstances; and,

10 aa. such other acts or omissions constituting negligence and carelessness as
11 may appear during the course of discovery or at the trial of this matter

12 23. As a direct and proximate result of the negligent and/or recklessness and/or
13 wanton acts and/or omissions of Defendants, Plaintiff LISA NIELSEN suffered serious physical
14 injury, pain and suffering and severe mental and emotional distress and economic loss and harm.

15 WHEREFORE, Plaintiffs pray for relief as set forth below.

16
17 **SECOND CAUSE OF ACTION**

18 **STRICT PRODUCTS LIABILITY**

19 24. Plaintiff incorporates Paragraphs 1 to 23 above as though fully set forth herein.

20 25. As a result of the unreasonably dangerous and defective condition of the products
21 used for uterine morcellation, including the Gyrus Power Morcellator, which Defendants
22 manufactured, designed, labeled, marketed, distributed, supplied and/or sold, and/or placed into
23 the stream of commerce, they are strictly liable to the Plaintiff LISA NIELSEN for her injuries
24 which they directly and proximately caused, based on the following:

25 a. failing to properly and adequately design the products used for uterine
26 morcellation,

27 b. failing to properly and adequately manufacture the products used for
28 uterine morcellation; and,

1 c. such other defects as shall be revealed in the course of discovery.

2 26. In addition, the aforesaid incident and Plaintiff LISA NIELSEN's injuries and
3 losses were the direct and proximate result of the use the Gyrus Power Morcellator in the way
4 in which it was intended. Defendants manufactured, designed, labeled, marketed, distributed,
5 supplied, sold and/or placed into the stream of commerce the products to be used for uterine
6 morcellation, without proper and adequate warnings regarding the potential for said products'
7 harm to humans and as otherwise set forth supra, when said Defendants knew or should have
8 known of the need for such warnings and/or recommendations.

9 WHEREFORE, Plaintiff prays for relief as set forth below.

10
11 **THIRD CAUSE OF ACTION**

12 **BREACH OF EXPRESS WARRANTY**

13 27. Paragraphs 1 through 26 are incorporated by this reference into this cause of
14 action as if they were set forth in full.

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

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

21 30. As a direct and proximate result of the negligent and/or reckless and/or wanton
22 acts and/or omissions of Defendants, plaintiff suffered serious physical injury, pain and suffering
23 and severe mental and emotional distress and economic loss and harm.

24 WHEREFORE, Plaintiff prays for relief as set forth below.

25
26 **FOURTH CAUSE OF ACTION**

27 **BREACH OF IMPLIED WARRANTY**

28 31. Paragraphs 1 through 30 are incorporated by this reference into this cause of

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1 action as if they were set forth in full.

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

4 33. At all relevant times, Defendants intended that the products used for uterine
5 morcellation be used in the manner that the Plaintiff's surgeons in fact used it and Defendants
6 impliedly warranted that product to be of merchantable quality, safe and fit for such use, and was
7 adequately tested.

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

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

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

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

22 35. In reliance upon defendants' implied warranty, Plaintiff's surgeons used said
23 products as prescribed and in the foreseeable manner normally intended, recommended,
24 promoted, instructed, and marketed by Defendant.

25 36. Defendants breached their implied warranty to Plaintiff in that said products used
26 for uterine morcellation were not of merchantable quality, safe and fit for their intended use, or
27 adequately tested.

28 37. As a direct and proximate result of the negligent and/or reckless and/or wanton

1 act and/or omissions of Defendants, plaintiff suffered serious physical injury, pain, and suffering
2 and severe mental and emotional distress and economic loss and harm.

3 WHEREFORE, Plaintiff prays for relief as set forth below.

4
5 **FIFTH CAUSE OF ACTION**

6 **FRAUDULENT MISREPRESENTATION AND OMISSION**

7 38. Plaintiff incorporates by this reference, as if fully set forth herein, each and every
8 allegation set forth in the preceding paragraphs.

9 39. Defendants, having undertaken the design, formulation, testing, manufacture,
10 marketing, sale, and distribution of devices used for uterine morcellation owed a duty to provide
11 accurate and complete information regarding said devices.

12 40. Prior to Plaintiff LISA NIELSEN undergoing her surgery, Defendants
13 fraudulently misrepresented, that the use of their device for uterine morcellation was safe and
14 effective.

15 41. Defendants had a duty to provide plaintiff LISA NIELSEN, physicians, and other
16 customers with true and accurate information regarding the devices for uterine morcellation it
17 manufactured, marketed, distributed and sold.

18 42. Defendants made representations and failed to disclose material facts with the
19 intent to induce consumers, including plaintiff, LISA NIELSEN, and the medical community to
20 act in reliance by purchasing and using the uterine morcellation sold by defendant.

21 43. Plaintiff LISA NIELSEN justifiably relied on her medical provider's use of the
22 Gyrus Power Morcellator during plaintiff's hysterectomy due to Defendants' representations and
23 omissions.

24 44. Defendants' representations and omissions regarding use of its uterine
25 morcellation devices were a direct and proximate cause of plaintiff's injuries. Plaintiff did not
26 discover Defendants' fraud until a date within the last three years.

27 45. As a direct and proximate result of the fraud of Defendants, plaintiff suffered
28 serious physical injury, pain and suffering and severe mental and emotional distress and

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1 economic loss and harm.

2 46. Because of Defendants' fraud as described herein, plaintiff is entitled to an award
3 of punitive damages against Defendants.

4 WHEREFORE, Plaintiff prays for relief as set forth below.

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6 **SIXTH CAUSE OF ACTION**

7 **LOSS OF SERVICES**

8 47. Paragraphs 1 through 46 are incorporated by this reference into this cause of
9 action as if they were set forth in full.

10 48. Plaintiff, KURT NIELSEN is the spouse of plaintiff LISA NIELSEN and as such
11 is entitled to the services, society, companionship, consortium and support of the plaintiff LISA
12 NIELSEN.

13 49. By reason of the foregoing acts and omission by the defendants, plaintiff KURT
14 NIELSEN, was deprived of the services, society, companionship, consortium, and support of
15 plaintiff, LISA NIELSEN.

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WHEREFORE, Plaintiffs pray for relief as follows:

- a. Compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, loss of services, consortium, society and other non-economic damages in the amount of \$5,000,000.00;
- b. Economic damages in an amount to be determined at trial of this action;
- c. Double or triple damages as allowed by law;
- d. Restitution and disgorgement of profits;
- e. Reasonable attorneys' fees
- f. Punitive damages;
- g. The costs of these proceedings;
- h. Prejudgment interest; and
- i. Such other and further relief as this Court deems just and proper

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DATED: September 19, 2014

Robert L. Clarkson
Michael J. Riley
Attorneys for Plaintiffs

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
Lisa Nielsen and Kurt Nielsen
(b) County of Residence of First Listed Plaintiff Nevada
(c) Attorneys (Firm Name, Address, and Telephone Number)
Clarkson Riley LLP
1880 Century Park East, 12th Floor
Los Angeles, CA 90067

DEFENDANTS
GYRUS ACMI, LP, a Minnesota Limited Partnership; GYRUS ACMI, LLC, a Minnesota Limited Liability Company; and DOES 1-50
County of Residence of First Listed Defendant Placer
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
2 U.S. Government Defendant
3 Federal Question (U.S. Government Not a Party)
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)
Citizen of This State PTF DEF
Citizen of Another State
Citizen or Subject of a Foreign Country

Table with 5 columns: CONTRACT, REAL PROPERTY, TORTS, CIVIL RIGHTS, PRISONER PETITIONS, FORFEITURE/PENALTY, LABOR, IMMIGRATION, BANKRUPTCY, SOCIAL SECURITY, FEDERAL TAX SUITS, OTHER STATUTES. Contains various legal categories and checkboxes.

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:
Product Liability

VII. REQUESTED IN COMPLAINT:
CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.
DEMAND \$ 5,000,000.00
CHECK YES only if demanded in complaint:
JURY DEMAND: X Yes [] No

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

DATE 09/19/2014
SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY
RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE