NANCY HERSH, CA State Bar No. 49091
nhersh@hershlaw.com
MARK E. BURTON, JR., CA State Bar No. 178400
mburton@hershlaw.com
HERSH & HERSH
A Professional Corporation
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102-6316
(415) 441-5544

Attorneys for Plaintiffs

HERSH AND HERSH
A Professional Corporation

IN THE UNITED STATES DISTRICT COURT

FOR THE NORTHERN DISTRICT OF CALIFORNIA

KATHLEEN TREMBLAY and HARRY TREMBLAY,

Plaintiffs,

v.

INTUITIVE SURGICAL, INC.,

Defendant.
_____ /

CASE NO. C 13 0231 MEJ

COMPLAINT;

DEMAND FOR JURY TRIAL

Plaintiffs, complaining of the defendant by their attorney, respectfully allege, upon information and belief, the following:

THE PARTIES

1. The plaintiff, KATHLEEN TREMBLAY, is a resident of and domiciled in Springfield, Oregon.

2. The plaintiff, HARRY TREMBLAY, is a resident of and domiciled in Springfield, Oregon.

3. Plaintiffs are husband and wife.

4. The defendant, INTUITIVE SURGICAL, INC., (hereinafter "INTUITIVE") is a foreign business corporation, duly organized and existing under and by virtue of the laws of the State of Delaware with a principal place of business in the State of California.

JURISDICTION AND VENUE

5. Jurisdiction for this action in the United States District Court arises under 28 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on complete diversity of citizenship in that the surgery performed on KATHLEEN TREMBLAY, a resident of Oregon, but a machine sold and distributed under the laws of Delaware by a corporation with its principal place of business in the State of California. The amount in controversy exceeds $75,000, exclusive of costs and interest.

GENERAL ALLEGATIONS

6. Plaintiff KATHLEEN TREMBLAY was advised that she needed to have a hysterectomy performed for uterine cancer on February 22, 2010.

7. Her physician presented her with information and materials promoting the benefit of da Vinci robotic hysterectomy over all other methods of surgery. Specifically, her physicians told her that due to the da Vinci robotic approach, she would heal faster, have a better outcome and have less pain.

8. Based on the representations made by her physicians and the written materials provided to her, the Plaintiff agreed to proceed with da Vinci robotic hysterectomy. Plaintiff KATHLEEN TREMBLAY underwent surgery, which resulted in damage, including vaginal cuff dehiscence and spread of the cancer to the abdominal wall.

9. KATHLEEN TREMBLAY continues to suffer from her injuries. Plaintiffs discovered that the cause of their injuries and damages was the da Vinci robot within the last two years. Through this time period, KATHLEEN TREMBLAY has been unable to maintain normal intimate relationships with HARRY TREMBLAY and has suffered emotional distress.

10. Due to the injuries sustained during and as a result of the da Vinci Robotic hysterectomy, Plaintiff KATHLEEN TREMBLAY had to have multiple painful additional medical tests and procedures and physician consultations and additional surgery and has suffered pain, loss of function, emotional distress, and permanent injury. Plaintiff HARRY TREMBLAY has suffered loss of consortium.

11. Defendant INTUITIVE is a Delaware corporation with its principal place of business in Sunnyvale, California.

12. Defendant INTUITIVE is a publically traded company on the NASDAQ exchange, with a current market value of more than two billion dollars.

13. Defendant designed, manufactured, tested, sold, promoted and labeled the da Vinci surgical robot.

14. On its website, Defendant asserts that it is the global technology leader in surgical robotic products.

15. The said robotic device is used in hospitals for a variety of surgeries, including gynecological, and including therein hysterectomies.

16. Defendant has promoted its device as (a) safe, and (b) safer than other comparative methods of surgery including, in the case of hysterectomies, laparoscopy, vaginal surgery and open surgery.

17. Defendant utilizes prominent websites aimed at consumers, seeking to create demand for the use of its robotic device by patients who consult surgeons.

18. Defendant sold it device through a calculated program of intimidation and market management, forcing hospitals and physicians to purchase it in order to appear to be competitive, and creating a fear in their minds that if they did not have this technology they would lose business to competitors.

19. Defendant reinforced its calculated program, as stated in the preceding

paragraph, by placing, on its website for potential patients, names of certain physicians who had performed 20 surgeries with the device.

20. The use of Defendant's robotic device in surgery presents substantial risks of complications and injuries, including de-vascularization of the vaginal cuff impeding healing, partial thermal injury burns to bowel, post-surgical abscesses, tears, dehiscences, bleeding, hematomas, sepsis, and fistulas.

21. More specifically, Defendant's robotic device can cause damage to the bowel, blood vessels, arteries, ureters, bladder, vaginal cuff, and other surrounding tissue.

22. In addition, due to lengthened time of surgery, patients are unnecessarily exposed to anesthesia for a dangerous period of time.

23. On occasion, these complications and injuries cause and/or contribute to infectious processes from thermal injury causing abscess formation and can lead to the untimely and premature death of the patient from that and other injuries caused by the device.

24. Defendant is aware of the aforesaid risks and complications associated with the use of the said robotic device.

25. Defendant does not provide adequate warnings to physicians and patients about the risks and complications associated with the use of its robotic device.

26. Defendant has not done, nor sponsored, adequate testing on its said device before and after marketing it to determine whether in random tests its said device is either safer or more effective or otherwise superior to other surgical and laparoscopic methods to which it compares itself.

27. Defendant has not done adequate post marketing surveillance of complications and injuries that have occurred in actual practice.

28. Defendant has not done, nor sponsored, any testing as to long-term outcomes, in comparison to other surgical and laparoscopic methods.

29. Defendant has not revealed, through publications or reports to the Food and Drug Administration and other governmental bodies, the true extent of complications and injuries, which have occurred in actual practice.

30. Defendant has suppressed reports and complaints of complications and performance errors due to the use of its said device.

31. Defendant does not adequately train physicians nor proctor them properly on the use of its device, thereby inducing them to cause complications and injuries, which would be avoided in the hands of properly trained physicians.

32. Defendant represents that they will have skilled technicians in the operating room or on emergency call in the event of problems arising with its said device, but often has neglected to do so.

33. Defendant has over-promoted its device to hospitals, physicians and the public, including potential consumers, combined with minimizing the risks and complications associated with its use.

34. The device is defective in that it relies upon the use of monopolar energy to cut, burn and cauterize tissue, whereas safer methods are available, such as bipolar energy and ultrasonic energy, which would reduce substantially the risk of complications.

35. The device has inadequate insulation for its arms, thereby allowing electrical current to pass into tissue outside of the operative field.

36. The insulation on the shafts of the said device becomes torn and worn in places, without the awareness of the physician user, allowing electrical current to pass into tissue outside of the operative field, causing damage.

37. Defendant has failed to warn users and consumers of the said robotic device about the inadequate insulation on the arms and the potential for electrical current to pass into tissue outside of the operative field.

38. Due to design defects, Defendant's devices have malfunctioned during the course of operative use causing injury, including the necessity of converting the procedure into open surgery, or often requiring subsequent surgeries to deal with complications of robotic use.

39. Defendant has failed to warn users and consumers of its said device of the design flaws stated in the preceding paragraphs, although it has reached out directly to consumers to promote its asserted advantages.

40. Defendant had specific knowledge and awareness of the dangers of monopolar current and that there were safety modalities commercially available that could have greatly diminished or eliminated some of these risks, yet the Defendant elected not to include these safety features on the da Vinci Robotic Hysterectomy platform.

41. Defendant has obtained and continues to maintain approval of the uses of its device from the Food and Drug Administration by failing to fully inform them of its knowledge of risks and complications associated with the use of its device.

FIRST CAUSE OF ACTION – PRODUCT LIABILITY

42. Plaintiffs incorporate by reference each and every paragraph of this Complaint as though set forth in full in this cause of action.

43. Defendant placed into the stream of commerce its aforesaid device which was defective in design, as previously pleaded.

44. Defendant owed Plaintiffs a duty to exercise reasonable care when designing, testing, manufacturing, marketing, advertising, promoting, distributing, and/or selling da Vinci Robots for hysterectomy.

45. At all relevant times to this action, Defendant owed a duty to properly warn Plaintiffs, the medical community, and the Public of the risks, dangers and adverse side effects of the da Vinci Robotic hysterectomy platform.

46. Defendant breached its duty by failing to exercise ordinary care in the

preparation, design, research, testing, development, manufacturing, inspection, labeling, marketing, promotion, advertising and selling of da Vinci Robotic Surgery, as set forth below:

a. failing to test da Vinci Robotic Hysterectomy properly and thoroughly before promoting the robotic surgical platform using monopolar current to the market;

b. failing to analyze properly and thoroughly the data resulting from the pre-marketing tests of monopolar current used in the da Vinci Robotic Hysterectomy;

c. failing to report to the FDA, the medical community, and the general public those data resulting from pre- and post-marketing tests of the da Vinci Robotic Hysterectomy platform which indicated risks associated with its use;

d. failing to conduct adequate post-market monitoring and surveillance of post-surgical complications associated with the da Vinci Robotic Hysterectomy platform using monopolar current;

e. failing to conduct adequate analysis of adverse event reports;

f. designing, manufacturing, marketing, advertising, distributing and promoting the da Vinci Robotic Hysterectomy directly to consumers, including Plaintiff, without adequate warning of the significant and dangerous risks of monopolar current and the da Vinci Robotic Hysterectomy Platform and without proper instructions to avoid the harm which could foresee ably occur as a result of using monopolar energy on the existing da Vinci Robotic Hysterectomy platform;

g. failing to exercise due care when advertising and promoting da Vinci Robotic Hysterectomy;

h. negligently continuing to manufacture, market, advertise, and promote da Vinci Robotic Hysterectomy after Defendant knew or should have known of the risks of serious injury and/or death associated with using monopolar current to perform certain aspects of the surgery including the colpotomy incision;

i. failing to use due care in the preparation and development of the da Vinci Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals through the use of monopolar current;

j. failing to use due care in the design of the da Vinci Robotic Hysterectomy platform with special regard to the insulation of the robotic arms and instruments to prevent the aforementioned risk of injuries to individuals during the routine course of surgery;

k. failing to conduct adequate pre-clinical testing and research to determine the safety of the use of monopolar current and the insulation of the robotic instruments to be used in robotic hysterectomy, with special regard to the reusing of the instruments up to ten times in ten different patients;

l. failing to conduct adequate intra-operative surveillance and post-operative complication studies to determine the safety of the use of monopolar energy during the surgical robotic hysterectomy procedure taught by INTUITIVE SURGICAL, INC., while Defendant knew or should have known that intra-operative surveillance and post-operative complication analysis would be the only means to determine the relative risk of using monopolar during important surgical steps when performing a robotic hysterectomy with specific attention to the risks of performing a colpotomy incision or an amputation of the uterus, causing severe thermal injury to bladder, ureter, bowel, vaginal cuff, and blood vessels, in the absence of clinical trials which cannot be conducted for this purpose, and that such surveillance would be necessary for a due diligence program that would alert Defendant to the need to change the technique for the use of monopolar current or to withdraw it from the market altogether;

m. failing to completely, accurately and in a timely fashion, disclose the results of the pre-marketing testing of issues with monopolar energy and post-marketing surveillance of monopolar energy related injuries and complications to Plaintiff, consumers, the medical community, and the FDA;

n. failing to accompany marketing materials promoting the da Vinci Robotic Hysterectomy platform using monopolar current with proper warnings regarding all possible adverse side effects associated with the use of the same;

o. failing to use due care in the manufacture, inspection, and safety evaluation of the da Vinci Robotic Hysterectomy platform to prevent the aforementioned risk of injuries to individuals who underwent a da Vinci Robotic Hysterectomy;

p. failing to use due care in the promotion of da Vinci Robotic Hysterectomy to prevent the aforementioned risk of injuries to individuals when the robotic arms were utilized in the performance of surgery;

q. failing to use due care in the sale and marketing of the da Vinci Robot to prevent the aforementioned risk of injuries to individuals who were to undergo robotic hysterectomy;

r. failing to use due care in the selling of the monopolar scissors to prevent the aforementioned risk of injuries to individuals who underwent da Vinci Robotic Hysterectomy;

s. failing to provide adequate and accurate training and information to the sales representatives who sold the da Vinci Robot;

t. failing to provide adequate and accurate training and information to healthcare providers for the appropriate use of the da Vinci Robot for hysterectomy;

u. failing to conduct or fund research into the development of safer robotic surgical instruments which would pose the least risk of causing severe thermal injury to bowel, bladder, ureter, and blood vessels and/or risk of leaving tissue behind;

v. failing to educate healthcare providers and the public about the safest use of the monopolar scissors in da Vinci Robotic surgery;

w. failing to give healthcare providers adequate information to weigh the risks of serious injury and/or death for a given patient using the da Vinci Robotic Hysterectomy platform and technique featuring the use of monopolar current; and,

x. being otherwise reckless, careless and/or negligent.

47. Defendant placed into the stream of commerce its aforesaid device, which was defective in its labeling and warnings, as previously pleaded.

48. Defendant placed into the stream of commerce its aforesaid device, which was defective in its testing and approval, as previously pleaded.

49. At the time the device left the possession of defendant it was in an unreasonably dangerous and defective condition for application for robotic hysterectomy using monopolar energy.

50. Despite the fact that Defendant knew or should have known that the da Vinci Robotic Hysterectomy platform using monopolar current had increased the risk of serious injury and/or death, Defendant continued to promote and market the da Vinci Robotic Hysterectomy to consumers, including Plaintiff, when safer and more effective methods of treatment were available.

51. The Defendant designed, tested, manufactured, packaged, marketed, distributed, promoted, and sold the da Vinci Robot, placing the da Vinci Robotic Hysterectomy into the stream of commerce.

52. The da Vinci Robot was designed, tested, inspected, manufactured, assembled, developed, labeled, sterilized, licensed, marketed, advertised, promoted, sold, packaged, supplied and/or distributed by Defendant in a defective and unreasonably dangerous condition to consumers, including the Plaintiff.

53. The da Vinci Robot was expected to reach, and did reach, users and/or consumers, including Plaintiff, without substantial change in the defective and unreasonably dangerous condition in which it was manufactured and sold.

54. Plaintiff's surgeon used the da Vinci robotic Hysterectomy platform, including monopolar current, as instructed by and certified by and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant. Plaintiff's surgeons, attended

a surgical lab for hands-on initial training and were proctored for by a proctor employed by INTUITIVE.

55. The da Vinci Robotic Hysterectomy platform was unreasonably dangerous in that, as designed, it failed to perform safely when used by ordinary consumers, including Plaintiff's surgeon, including when it was used as intended and in a reasonably foreseeable manner.

56. The da Vinci Robotic Hysterectomy was unreasonably dangerous in that, as designed, the risks of serious injury and/or death, including bowel, bladder, ureteral, vaginal cuff, abscess formation, permanent scarring, or vascular injury, posed by its monopolar current risks exceeded any benefit the Robotic approach was designed to or might in fact bestow.

57. The da Vinci Robotic Hysterectomy platform was unreasonably dangerous in that, as designed, it was dangerous to an extent beyond that contemplated by the medical community, and ordinary regulars, including the Plaintiff.

58. The da Vinci Surgical Robot was defective in its design in that it neither bore, nor was packaged with, nor accompanied by, warnings adequate to alert the medical community, including Plaintiff's surgeon, to the risks described herein, including, but not limited to, the risk of serious injury and/or death, including bowel, bladder, ureteral, vaginal cuff devascularization, or vascular injury, posed by its monopolar current risks. The da Vinci Robot was not accompanied by adequate labeling, instructions for use and/or warnings to fully apprise the medical, hospital, operating room and/or scientific communities, and potential patients, including Plaintiff, of the potential risks and serious side effects associated with its use, thereby rendering Defendant liable to the Plaintiff.

59. There were safer alternative energy modalities available including bipolar energy and ultrasonic energy.

60. Monopolar energy, as used and taught on the da Vinci Robotic Hysterectomy platform, was unsafe for normal or reasonably anticipated use in performing the colpotomy incision or the amputation of the uterus.

61. In light of the potential and actual risk of harm associated with the use of monopolar energy so close to bowel, bladder, ureter, vaginal cuff, and blood vessels, a reasonable person who had actual knowledge of this potential and actual risk of harm would have concluded that the da Vinci Robotic Hysterectomy platform should not have been marketed in that condition.

62. Although Defendant knew or should have known of the defective nature of its da Vinci Robotic Hysterectomy platform using monopolar current, it continued to design, manufacture, market, and promote the use of its da Vinci Robotic Hysterectomy platform so as to maximize sales and profits at the expense of the public health and safety. Defendant thus acted with conscious and deliberate disregard of the foreseeable harm caused by the continued use of monopolar energy on its robotic platform.

63. Plaintiff could not, through the exercise of reasonable care, have discovered the risk of serious injury and/or death associated with and/or caused by the da Vinci Robotic Hysterectomy platform featuring monopolar current. Plaintiff, if aware of these additional risks, could have chosen surgical procedures with similar efficacies but without these additional risks. As a result, Plaintiff suffered the personal injuries described herein.

64. Information given by Defendant to the medical community and to the consumers concerning the safety and efficacy of the da Vinci Robotic Hysterectomy platform, especially the information contained in the advertising and promotional materials, did not accurately reflect the serious and potentially fatal side effects.

65. Had adequate warnings and instructions been provided, Plaintiff's surgeon would not have suggested a robotic approach, and Plaintiff would have had at a much lower risk of the harmful side effects described herein.

66. As a direct and proximate consequence of Defendant's negligence, willful, wanton, and/or intentional acts, omissions, misrepresentations and/or otherwise culpable acts described herein, Plaintiff KATHLEEN TREMBLAY sustained injuries and damages alleged herein.

67. That by reason of the foregoing and defendant's aforesaid conduct, among other things, Plaintiff KATHLEEN TREMBLAY suffered injuries which caused her to undergo additional surgery and medical procedures, endured pain and suffering and will continue to do so in the future, has suffered mental anguish and will continue to do so in the future, has loss the pleasure of sexual activity, and has incurred medical expenses.

68. Plaintiff has incurred and Defendant is liable for certain expenses, including hospital, surgical and medical treatment, transportation costs to University Centers, as a result of, among other things, Defendant's conduct.

69. As a result of its said conduct, Defendant has become strictly liable to Plaintiff.

70. Defendant's conduct in continuing to market, sell and distribute the aforesaid devices after obtaining knowledge they were defective and not performing as represented and intended, showed complete indifference to and/or a conscious disregard for the safety of others justifying an award of punitive damages for aggravating circumstances in such a sum which will serve to deter Defendant and others from similar conduct in the future.

WHEREFORE, Plaintiffs demand judgment against Defendant and seek compensatory damages, and exemplary and punitive damages, together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SECOND CAUSE OF ACTION – GENERAL NEGLIGENCE & NEGLIGENT TRAINING & PROCTORING & NEGLIGENT CERTIFICATION

71. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action contained herein as if the same were set forth more fully at length herein.

72. Defendant was careless in the design, testing, manufacturing, labeling and promotion of its aforesaid device, as pleaded in previous paragraphs.

73. In specific, Defendant failed to warn users and consumers of the risk of complications associated with the use of its said device, risks of monopolar current use,

including the damage to the bladder, bowel, ureter, vaginal cuff, blood vessels and tissues within the surgical site, which was a proximate cause of Plaintiff's KATHLEEN TREMBLAY's additional surgeries and medical treatments resulting in long-term pain and suffering.

74. Defendant took it upon itself to "train" and "certify" Plaintiff's surgeon on the use of the da Vinci Robotic Hysterectomy platform using monopolar current. Upon belief the Defendant specifically trained Plaintiff's surgeon on the use of monopolar current via operative endoshear scissors during the dissection of the bladder and the colpotomy incision causing thermal injury and devascularization of the vaginal cuff leading to increased tissue damage, abscess, and chronic inflammatory changes.

75. Defendant did not properly proctor and/or properly instruct Plaintiff's surgeons and attending staff as to the safe use of its device nor how to detect complications which its said device causes and is known to cause.

76. Defendant had a financial incentive to promptly train, proctor, and certify Plaintiff's surgeon without regard to whether or not Plaintiff's surgeon was truly skilled and competent on the da Vinci Robotic Hysterectomy platform.

THIRD CAUSE OF ACTION – FRAUD

77. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

78. Defendant misrepresented the safety and comparative efficacy of its device, upon which Plaintiff's surgeons relied, to Plaintiff's detriment.

79. Defendant misrepresented the safety and comparative efficacy of its device, upon which the hospital and surgery department where Plaintiff was operated on relied, in purchasing and using the device, to Plaintiff's detriment.

80. Defendant was aware, or should have been aware, of the known dangers of

monopolar current in regard to unsuspected current leaving the shaft of a poorly insulated instrument. Furthermore, Defendant suggested to Hospitals that multiple uses of the robotic instruments could be done yet Defendant did so without regard to re-testing of the insulation along the shaft of their robotic instruments or at the wrist of the robotic instrument.

81. Defendant was aware, or should have been aware, of the known dangers of monopolar current in regard to capacitive coupling, which like insulation failure can cause a thermal injury to occur in adjacent structures like bowel, bladder, ureter, vaginal cuff, or blood vessel. Defendant was aware, or should have been aware, of the known increased incidence of vaginal cuff dehiscence, de-vascularization and abscess formation due to the use of monopolar current while performing the colpotomy portion of the da Vinci Robotic total laparoscopic hysterectomy.

82. Defendant was aware that there were safer energy modalities including ultrasonic energy and bipolar energy, yet maintained teaching the use of monopolar current in the da Vinci Robotic Hysterectomy. Defendant did so based on not wanting to pay for the cost of having to license these safer energy technologies.

83. Defendant was also aware, or should have been aware, of the Active Electrode Monitoring System, or AEM Technology, which shields and monitors instruments continuously directing stray energy, the cause of stray electrosurgical burns, away from the patient. With the AEM system, the patient is never at risk for stray electrosurgical burns due to insulation failure and capacitive coupling. Despite having specific knowledge of this safety system, the Defendant choose not to purchase it for its da Vinci Robotic Hysterectomy platform using monopolar current.

84. Further, Defendant concealed from consumers and users, including those mentioned in the preceding paragraphs, the risks of complications of which it was aware, which would have been material to consumers and users in making the decision to use the said device.

85. Further, Defendant suppressed reports of adverse outcomes with the use of its

device, which would have been material to consumers and users in making the decision to use the said device.

86. Further, Defendant over-promoted its device and minimized its risks, for the purpose of making sales of its device, its maintenance, and the use of replaceable parts, and skewed the cost-benefit ratio inaccurately in its favor.

87. The said conduct was so willful, wanton, malicious and reckless that it merits the imposition of punitive damages.

FOURTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY

88. Plaintiff repeats, reiterates and realleges each and every allegation and cause of action set forth herein as if the same were set forth more fully at length herein.

89. Defendant made express warranties of safety to the buyers and consumers of the device utilized during Plaintiff KATHLEEN TREMBLAY's surgery, upon which the buyers and users, as agents of Plaintiff KATHLEEN TREMBLAY, relied, to her detriment. Defendant expressly represented to the Plaintiff KATHLEEN TREMBLAY (and to other consumers and the medical community) that the da Vinci robotic hysterectomy was safe, efficacious and fit for its intended purposes that it was of merchantable quality, that it did not produce any unwarned-of dangerous side effects, and that it was adequately tested.

90. Defendant breached expressed warranties with respect to the da Vinci robotic hysterectomy in the following ways:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, surgeon training sessions, publications, notice letters, and regulatory submissions that the da Vinci Robotic hysterectomy was safe, and fraudulently withheld and concealed information about the substantial risks or serious injury and/or death associated with using monopolar current on the existing da Vinci robotic platform;

b. Defendant represented that the da Vinci Robotic Hysterectomy was as

safe and/or safer than alternative surgical methods, and fraudulently concealed information which demonstrated that the da Vinci robotic hysterectomy approach was not safer than alternatives available on the market; and,

c. Defendant represented that the da Vinci Robotic Hysterectomy was more efficacious than other alternative surgical methods, and fraudulently concealed information that it was not more efficacious than alternative surgical methods.

91. Da Vinci Robotic Hysterectomy does not conform to Defendant's express representations, because it is not safe, efficacious, has numerous serious unwarned-of side effects, causes severe and permanent injuries including death, and was not adequately tested.

92. The da Vinci Robotic Hysterectomy platform, including the use of monopolar current, did not perform as safely as an ordinary physician, as an agent of the patient, would have expected when used as intended or in a reasonably foreseeable manner.

93. Plaintiff KATHLEEN TREMBLAY, her surgeons and other in the medical community, relied upon Defendant's express warranties, resulting in the Plaintiff's da Vinci Robotic Hysterectomy.

94. Plaintiff, after ascertaining through her own injuries that the da Vinci Robotic Hysterectomy violated express warranties, hereby supply notice to Defendant INTUITIVE SURGICAL, INC., of same through the filing of this lawsuit.

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

96. By selling the said device, Defendant made implied warranties of safety, merchantable quality, and fitness for use, which was breached when plaintiff KATHLEEN TREMBLAY was injured during surgery.

97. As a further direct and proximate result of the acts of Defendant, Plaintiffs suffered emotional distress.

WHEREFORE, Plaintiffs demand judgment against Defendant and seeks compensatory

damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

FIFTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY

98. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

99. At all relevant and material times, Defendant manufactured, distributed, advertised, promoted, and sold the da Vinci Robot.

100. At all relevant times, Defendant intended that the da Vinci Robot be used in the manner that the Plaintiff's surgeon in fact used it and Defendant impliedly warranted the product to be of merchantable quality, safe and fit for such use, and was adequately tested.

101. Defendant breached various implied warranties with respect to the da Vinci Robot including the particulars:

a. Defendant represented through its labeling, advertising, marketing materials, detail persons, seminar presentations, publications, notice letters, and regulatory submissions that the da Vinci Robotic Hysterectomy platform was safe and fraudulently withheld and concealed information about the substantial risks of serious injury and/or death associated with using the da Vinci Robot with monopolar current;

b. Defendant represented that the da Vinci Robotic Hysterectomy with monopolar current was as safe and/or safer than other alternative surgical approaches that did not include the use of the da Vinci Robot, and fraudulently concealed information, which demonstrated that the da Vinci Robotic Hysterectomy was not safer than alternatives available on the market; and,

c. Defendant represented that the da Vinci Robotic Hysterectomy was as more efficacious than other alternative surgical approaches and techniques and fraudulently concealed information, regarding the true efficacy of the robotic hysterectomy with monopolar

current.

102. In reliance upon Defendant's implied warranty, Plaintiff's surgeon used the da Vinci Robotic Hysterectomy platform as prescribed and in the foreseeable manner normally intended, recommended, promoted, instructed, and marketed by Defendant.

103. Defendant breached its implied warranty to Plaintiff in that the da Vinci Robotic Hysterectomy platform with monopolar current was not of merchantable quality, safe and fit for its intended use, or adequately tested.

104. 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.

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

Wherefore, Plaintiffs demand judgment against Defendant and seeks compensatory damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

SIXTH CAUSE OF ACTION - UNJUST ENRICHMENT

106. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

107. At all times relevant to this action, Defendant designed, advertised, marketed, promoted, manufactured, distributed, supplied, and/or sold the da Vinci Robot for hysterectomy use.

108. Plaintiff KATHLEEN TREMBLAY'S surgeon's hospital purchased the da Vinci Robot from the Defendant for the purpose of using it for Robotic Hysterectomy. The same hospital purchased disposable and reusable instrument for the performance of

KATHLEEN TREMBLAY'S surgery.

109. Defendant has accepted payment from said aforementioned hospital for both the da Vinci robot used in KATHLEEN TREMBLAY'S surgery, but also for the routine maintenance and per surgery cost of additional items including disposable items.

110. KATHLEEN TREMBLAY did not receive the safe and effective surgical product which she intended to purchase; nor did the hospital where KATHLEEN TREMBLAY had her surgery.

111. It is inequitable and unjust for Defendant to retain this money because the Plaintiff did not in fact receive the safe and efficacious surgical procedure Defendant represented da Vinci Robotic Hysterectomy to be.

WHEREFORE, Plaintiffs demand judgment against Defendant and seeks equitable relief, the costs of suit and attorneys' fees, and such other and further relief as this Court deems just and proper.

SEVENTH CAUSE OF ACTION-LOSS OF CONSORTIUM

112. Plaintiffs incorporate by reference each and every paragraph of this complaint as though set forth in full in this cause of action.

113. As a direct consequence of the injuries to the vaginal cuff and subsequent spread of cancer requiring multiple surgeries sustained by KATHLEEN TREMBLAY while undergoing a da Vinci Robotic Hysterectomy and the emotional consequences; Plaintiff HARRY TREMBLAY has been deprived the normal companionship, company, affection, regard, assistance, comfort, sexual relations, and emotional stability from his wife KATHLEEN TREMBLAY.

114. These physical and emotional consequences of the injuries have negatively impacted the quality and caused undo hardship to the marriage relationship.

Wherefore, Plaintiffs demand judgment against Defendant and seeks compensatory

damages, and exemplary and punitive damages together with interest, the costs of suit and attorneys' fees and such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiffs demand a trial by jury on all counts and issues so triable.

GLOBAL PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully demand judgment against Defendant on each count as follows:

1. On the First Cause of Action for Product Liability including personal injury and pain and suffering and emotional distress, the sum of $10 million;

2. On the Second Cause of Action for Negligence, the sum of $10 million;

3. On the Third Cause of Action for Fraud, the sum of $10 million;

4. On the Fourth & Fifth Cause of Action for Breach Of Express Warranty and Breach of Implied Warranty, the sum of $10 million;

5. On the Sixth Cause of Action for Unjust Enrichment, the sum of $200 million;

6. On the Seventh Count of Loss of Consortium, the sum of $10 million;

7. On the claim for punitive damages in each cause of action, a total of $20 million; and,

8. Reasonable attorney's fees when recoverable.

Such other additional and further relief to which Plaintiff may be justly entitled, in law or equity; all together with the interest, costs and disbursements of this action.

DATED: January 17, 2013.

HERSH & HERSH
A Professional Corporation

By _____
Nancy Hersh
Attorneys for Plaintiffs

HERSHANDHERSH
A Professional Corporation

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.)*

CIVIL COVER SHEET

I. (a) PLAINTIFFS

KATHLEEN TREMBLAY and HARRY TREMBLAY

(b) County of Residence of First Listed Plaintiff Lane County, Oregon
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys *(Firm Name, Address, and Telephone Number)*
Nancy Hersh, Hersh & Hersh, a Professional Corporation
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102 (415) 441-5544

DEFENDANTS

INTUITIVE SURGICAL, INC.

County of Residence of First Listed Defendant Santa Clara County, CA
(IN U.S. PLAINTIFF CASES ONLY)

NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED.

Attorneys *(If Known)*

C 13 0231

MEJ

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
- ☐ 110 Insurance
- ☐ 120 Marine
- ☐ 130 Miller Act
- ☐ 140 Negotiable Instrument
- ☐ 150 Recovery of Overpayment & Enforcement of Judgment
- ☐ 151 Medicare Act
- ☐ 152 Recovery of Defaulted Student Loans (Excludes Veterans)
- ☐ 153 Recovery of Overpayment of Veteran's Benefits
- ☐ 160 Stockholders' Suits
- ☐ 190 Other Contract
- ☐ 195 Contract Product Liability
- ☐ 196 Franchise

TORTS

PERSONAL INJURY
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers' Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Personal Injury - Medical Malpractice

PERSONAL INJURY
- ☒ 365 Personal Injury - Product Liability
- ☐ 367 Health Care/ Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Personal Injury Product Liability

PERSONAL PROPERTY
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

FORFEITURE/PENALTY
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

BANKRUPTCY
- ☐ 422 Appeal 28 USC 158
- ☐ 423 Withdrawal 28 USC 157

PROPERTY RIGHTS
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 840 Trademark

LABOR
- ☐ 710 Fair Labor Standards Act
- ☐ 720 Labor/Management Relations
- ☐ 740 Railway Labor Act
- ☐ 751 Family and Medical Leave Act
- ☐ 790 Other Labor Litigation
- ☐ 791 Employee Retirement Income Security Act

SOCIAL SECURITY
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

OTHER STATUTES
- ☐ 375 False Claims Act
- ☐ 400 State Reapportionment
- ☐ 410 Antitrust
- ☐ 430 Banks and Banking
- ☐ 450 Commerce
- ☐ 460 Deportation
- ☐ 470 Racketeer Influenced and Corrupt Organizations
- ☐ 480 Consumer Credit
- ☐ 490 Cable/Sat TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 890 Other Statutory Actions
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 895 Freedom of Information Act
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes

REAL PROPERTY
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

CIVIL RIGHTS
- ☐ 440 Other Civil Rights
- ☐ 441 Voting
- ☐ 442 Employment
- ☐ 443 Housing/ Accommodations
- ☐ 445 Amer. w/Disabilities - Employment
- ☐ 446 Amer. w/Disabilities - Other
- ☐ 448 Education

PRISONER PETITIONS

Habeas Corpus:
- ☐ 463 Alien Detainee
- ☐ 510 Motions to Vacate Sentence
- ☐ 530 General
- ☐ 535 Death Penalty

Other:
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Condition
- ☐ 560 Civil Detainee - Conditions of Confinement

IMMIGRATION
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions

FEDERAL TAX SUITS
- ☐ 870 Taxes (U.S. Plaintiff or Defendant)
- ☐ 871 IRS - Third Party 26 USC 7609

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 U.S.C. Sections 1332(a)(1) and 1332(c)(2

Brief description of cause:
personal injury; product liability; negligence; fraud; breach of express and implied warranty; unjust enrichment

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.

DEMAND $

CHECK YES only if demanded in complaint:
JURY DEMAND: ☒ Yes ☐ No

VIII. RELATED CASE(S) IF ANY *(See instructions)*:

JUDGE DOCKET NUMBER

DATE
01/17/2012

SIGNATURE OF ATTORNEY OF RECORD

IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2)

(Place an "X" in One Box Only) ☐ SAN FRANCISCO/OAKLAND ☑ SAN JOSE ☐ EUREKA

AO 440 (Rev. 12/09) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

Northern District of California

KATHLEEN TREMBLAY and HARRY TREMBLAY,

Plaintiff

v.

INTUITIVE SURGICAL, INC.

Defendant

Civil Action No. C 13 0231 MEJ

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

Intuitive Surgical, Inc.
c/o CT Corporation System,
Agent for Service of Process
818 West Seventh Street
Los Angeles, CA 90017

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:

Nancy Hersh
Mark E. Burton, Jr.
Hersh & Hersh, A Professional Corporation
601 Van Ness Avenue, Suite 2080
San Francisco, CA 94102

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: _____

Simone Voltz

Signature of Clerk or Deputy Clerk