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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. **13**
COMPLAINT;

DEMAND FOR JURY TRIAL

MEJ
0231

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.

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

4 **JURISDICTION AND VENUE**

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6 5. Jurisdiction for this action in the United States District Court arises under 28
7 U.S.C. Sections 1332(a)(1) and 1332(c)(2) as this is a civil action based on complete diversity
8 of citizenship in that the surgery performed on KATHLEEN TREMBLAY, a resident of
9 Oregon, but a machine sold and distributed under the laws of Delaware by a corporation with
10 its principal place of business in the State of California. The amount in controversy exceeds
11 \$75,000, exclusive of costs and interest.

12 **GENERAL ALLEGATIONS**

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

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

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

23
24 9. KATHLEEN TREMBLAY continues to suffer from her injuries. Plaintiffs
25 discovered that the cause of their injuries and damages was the da Vinci robot within the last
26 two years. Through this time period, KATHLEEN TREMBLAY has been unable to maintain
27 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 its 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

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

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

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

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

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

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

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

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

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

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27 28. Defendant has not done, nor sponsored, any testing as to long-term outcomes, in
28 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.

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

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

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

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

14 **FIRST CAUSE OF ACTION – PRODUCT LIABILITY**

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

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

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

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

25 46. Defendant breached its duty by failing to exercise ordinary care in the
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1 preparation, design, research, testing, development, manufacturing, inspection, labeling,
2 marketing, promotion, advertising and selling of da Vinci Robotic Surgery, as set forth below:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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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,

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

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

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

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

18 **THIRD CAUSE OF ACTION – FRAUD**

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

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

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

27 80. Defendant was aware, or should have been aware, of the known dangers of
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1 monopolar current in regard to unsuspected current leaving the shaft of a poorly insulated
2 instrument. Furthermore, Defendant suggested to Hospitals that multiple uses of the robotic
3 instruments could be done yet Defendant did so without regard to re-testing of the insulation
4 along the shaft of their robotic instruments or at the wrist of the robotic instrument.

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

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

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

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

27 85. Further, Defendant suppressed reports of adverse outcomes with the use of its
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1 device, which would have been material to consumers and users in making the decision to use
2 the said device.

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

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

9 **FOURTH CAUSE OF ACTION - BREACH OF EXPRESS WARRANTY**

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

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

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

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

27 b. Defendant represented that the da Vinci Robotic Hysterectomy was as
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1 safe and/or safer than alternative surgical methods, and fraudulently concealed information
2 which demonstrated that the da Vinci robotic hysterectomy approach was not safer than
3 alternatives available on the market; and,

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

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

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

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

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

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

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

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

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

3 **FIFTH CAUSE OF ACTION – BREACH OF IMPLIED WARRANTY**

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

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

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

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

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

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

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

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

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

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

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

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

19 **SIXTH CAUSE OF ACTION - UNJUST ENRICHMENT**

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

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

25 108. Plaintiff KATHLEEN TREMBLAY'S surgeon's hospital purchased the da
26 Vinci Robot from the Defendant for the purpose of using it for Robotic Hysterectomy. The
27 same hospital purchased disposable and reusable instrument for the performance of
28

1 KATHLEEN TREMBLAY'S surgery.

2 109. Defendant has accepted payment from said aforementioned hospital for both the
3 da Vinci robot used in KATHLEEN TREMBLAY'S surgery, but also for the routine
4 maintenance and per surgery cost of additional items including disposable items.
5

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

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

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

15 **SEVENTH CAUSE OF ACTION-LOSS OF CONSORTIUM**

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

18 113. As a direct consequence of the injuries to the vaginal cuff and subsequent spread
19 of cancer requiring multiple surgeries sustained by KATHLEEN TREMBLAY while
20 undergoing a da Vinci Robotic Hysterectomy and the emotional consequences; Plaintiff
21 HARRY TREMBLAY has been deprived the normal companionship, company, affection,
22 regard, assistance, comfort, sexual relations, and emotional stability from his wife KATHLEEN
23 TREMBLAY.
24

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

27 Wherefore, Plaintiffs demand judgment against Defendant and seeks compensatory
28

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

3
4 **DEMAND FOR JURY TRIAL**

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

6 **GLOBAL PRAYER FOR RELIEF**

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

- 9
- 10 1. On the First Cause of Action for Product Liability including personal injury and
11 pain and suffering and emotional distress, the sum of \$10 million;
 - 12 2. On the Second Cause of Action for Negligence, the sum of \$10 million;
 - 13 3. On the Third Cause of Action for Fraud, the sum of \$10 million;
 - 14 4. On the Fourth & Fifth Cause of Action for Breach Of Express Warranty and
15 Breach of Implied Warranty, the sum of \$10 million;
 - 16 5. On the Sixth Cause of Action for Unjust Enrichment, the sum of \$200 million;
 - 17 6. On the Seventh Count of Loss of Consortium, the sum of \$10 million;
 - 18 7. On the claim for punitive damages in each cause of action, a total of \$20
19 million; and,
 - 20 8. Reasonable attorney's fees when recoverable.

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

23 DATED: January 17, 2013.

24 HERSH & HERSH
A Professional Corporation

25
26 By 

27 Nancy Hersh
Attorneys for Plaintiffs

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 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) <div style="text-align: center; font-size: 2em; font-weight: bold;">C 13 0001</div> <div style="text-align: right; font-weight: bold; color: red;">MEJ</div>
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II. BASIS OF JURISDICTION (Place an "X" in One Box Only) <div style="display: flex; justify-content: space-between;"> <div style="width:48%;"> <input type="checkbox"/> 1 U.S. Government Plaintiff <input type="checkbox"/> 2 U.S. Government Defendant </div> <div style="width:48%;"> <input type="checkbox"/> 3 Federal Question (U.S. Government Not a Party) <input checked="" type="checkbox"/> 4 Diversity (Indicate Citizenship of Parties in Item III) </div> </div>	III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in one Box for Plaintiff and One Box for Defendant) <table style="width:100%; border-collapse: collapse;"> <tr> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DEF</th> <th></th> <th style="text-align: center;">PTF</th> <th style="text-align: center;">DEF</th> </tr> <tr> <td>Citizen of This State</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td style="text-align: center;"><input type="checkbox"/> 1</td> <td>Incorporated or Principal Place of Business In This State</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> <td style="text-align: center;"><input type="checkbox"/> 4</td> </tr> <tr> <td>Citizen of Another State</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 2</td> <td style="text-align: center;"><input type="checkbox"/> 2</td> <td>Incorporated and Principal Place of Business In Another State</td> <td style="text-align: center;"><input type="checkbox"/> 5</td> <td style="text-align: center;"><input checked="" type="checkbox"/> 5</td> </tr> <tr> <td>Citizen or Subject of a Foreign Country</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td style="text-align: center;"><input type="checkbox"/> 3</td> <td>Foreign Nation</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> <td style="text-align: center;"><input type="checkbox"/> 6</td> </tr> </table>		PTF	DEF		PTF	DEF	Citizen of This State	<input type="checkbox"/> 1	<input type="checkbox"/> 1	Incorporated or Principal Place of Business In This State	<input type="checkbox"/> 4	<input type="checkbox"/> 4	Citizen of Another State	<input checked="" type="checkbox"/> 2	<input type="checkbox"/> 2	Incorporated and Principal Place of Business In Another State	<input type="checkbox"/> 5	<input checked="" type="checkbox"/> 5	Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6
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Citizen or Subject of a Foreign Country	<input type="checkbox"/> 3	<input type="checkbox"/> 3	Foreign Nation	<input type="checkbox"/> 6	<input type="checkbox"/> 6																				

IV. NATURE OF SUIT (Place an "X" in One Box Only)					
CONTRACT <input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	TORTS PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input checked="" type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	FORFEITURE/PENALTY <input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	BANKRUPTCY <input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS -Third Party 26 USC 7609	OTHER STATUTES <input type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer. w/Disabilities - Employment <input type="checkbox"/> 446 Amer. w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 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 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
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VII. REQUESTED IN COMPLAINT:	<input type="checkbox"/> CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P.	DEMAND \$	CHECK YES only if demanded in complaint: JURY DEMAND: <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No
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VIII. RELATED CASE(S) IF ANY	(See instructions): JUDGE _____ DOCKET NUMBER _____
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DATE 01/17/2012	SIGNATURE OF ATTORNEY OF RECORD
IX. DIVISIONAL ASSIGNMENT (Civil L.R. 3-2) (Place an "X" in One Box Only) <div style="display: flex; justify-content: space-around; margin-top: 5px;"> <input type="checkbox"/> SAN FRANCISCO/OAKLAND <input checked="" type="checkbox"/> SAN JOSE <input type="checkbox"/> EUREKA </div>	

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. 13

MEJ
0231

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

Simone Voltz

Date: _____

Signature of Clerk or Deputy Clerk