

**UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK**

LAURA WOODFIELD,	:	
	:	Case No.: 17-cv- 4730
	:	
Plaintiff,	:	COMPLAINT
-against-	:	
	:	JURY TRIAL DEMANDED
ZIMMER US, INC., ZIMMER, INC.,	:	
ZIMMER HOLDINGS, INC., and	:	
ZIMMER ORTHOPAEDIC	:	
SURGICAL PRODUCTS, INC.,	:	
	:	
Defendants.	:	

COMES NOW Plaintiff LAURA WOODFIELD, who by and through the undersigned counsel, hereby submits this complaint against ZIMMER US, INC., ZIMMER, INC., ZIMMER HOLDINGS, INC., and ZIMMER ORTHOPAEDIC SURGICAL PRODUCTS, INC. for compensatory damages, and such other relief deemed just and proper arising from the injuries of Plaintiff, as follows:

PARTIES

1. At all times relevant hereto, Plaintiff LAURA WOODFIELD was a resident of the State of New York.
2. Defendant Zimmer, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located in Warsaw, Indiana at 345 East Main Street, Warsaw, Indiana 46581.
3. Defendant Zimmer Holdings, Inc. is a corporation organized and existing under the laws of Delaware, and has its principal place of business located at 345 East Main Street, Warsaw, Indiana 46581.

4. Defendant, Zimmer Holdings, Inc., is a corporation organized and existing under the laws of Delaware, and has its principal place of business located at 345 East Main Street, Warsaw, Indiana, 46581.

5. Defendant Zimmer Orthopaedic Surgical Products, Inc. is a corporation organized and existing under the laws of Ohio, and has its principal place of business in Dover, Ohio at 200 West Ohio Avenue, Dover, OH 44622.

6. The Zimmer branded Persona knee component was designed, manufactured and distributed by defendants, Zimmer US, Inc., Zimmer, Inc., Zimmer Holdings, Inc., and Zimmer Orthopaedic Surgical Products, Inc. (Collectively referred to as the “Defendants” or “Zimmer Defendants” herein).

7. At all times material hereto, the Zimmer Defendants developed, designed, tested, manufactured, distributed, marketed, and sold the Zimmer Persona Device that is the subject of this litigation.

JURISDICTION AND VENUE

8. This court has subject matter jurisdiction pursuant to 28 United States Code § 1332 as to the claims of the Plaintiff.

9. The amount in controversy alleged by each of the respective individual Plaintiff will exceed seventy-five thousand dollars (\$75,000.00).

**COMMON ALLEGATIONS
APPLICABLE TO ALL COUNTS**

THE ZIMMER PERSONA DEVICE GENERALLY

10. The Zimmer Persona knee replacement device was approved in 2012 through the FDA’s 510(k) process. The 510(k) process allows products to reach the market with limited to no testing, as long as the device is similar to something already approved and on the market.

Indeed, the application was filed with the U.S. Food and Drug Administration on June 15, 2012 under 510(k) application number K121771, and the device was approved on November 15, 2012. Therein, Zimmer claims predicate device similarity to the Zimmer NexGen knee system and the DePuy Attune Knee System. However, the Persona device that was approved in November 2012 involved a porous, uncemented tibial plate.

11. Approval of a device in this manner saves manufacturers a great deal of money as it requires a company only to show substantial similarity to a previous approved device, and therefore, does not require clinical testing on humans. Because of this, and because the Persona device is relatively new, there is no long-term data regarding the device.

12. The Persona knee system was distributed from November 2012 through January 2015 by Zimmer Inc., and was marketed by the Zimmer Defendants as “the Personalized Knee System” in their promotional materials.

13. According to Zimmer’s advertising materials, the Zimmer Persona Knee was “designed to minimize the compromises experienced with yesterday’s standard knee systems.” The system allows surgeons to personalize the implant to the unique needs of the patient, with a goal of coming as close as possible to the way a real human joint works, offering “unparalleled levels of personalization, empowering surgeons to restore the unique identity of every knee.”

14. Thus, the Zimmer Persona knee device was advertised and marketed as better than any device on the market at the time at mimicking the natural movement of the human knee. The goal was to provide younger, more active people an option when they needed knee replacement. Physicians, such as Plaintiff’s physicians, relied on these statements.

15. Unfortunately, despite being marketed as long lasting, after just three (3) years on the market, the Persona knee system has been linked to numerous failures and complications

from patients all over the United States, leading to an FDA recall of the Persona knee system in 2015.

16. The recall focused on the Persona's porous coated, uncemented Trabecular Metal Tibial Plate, one component of the overall Zimmer Persona Trabecular Knee System. The Tibial Plate is a metal part placed on the top of the patient's shinbone, or tibia, during knee replacement surgery. It is secured to the bone, where it produces a "platform" for the rest of the Persona system implant.

17. The Zimmer Persona's uncemented Trabecular Metal Tibial Plate is part of the Persona total knee implant system.

18. The subject uncemented Trabecular Metal implant consists of two pegs that, when inserted into the bone, will then grow into or become part of the bone. These pegs are supposed to give the implant stability. This is a deviation from prior knee replacement system designs that feature cemented tibial plates.

19. Indeed, if the plate is not seated properly, gaps between the plate and bone can occur, which appear in medical imaging as "radiolucent lines." These radiolucent lines are dark areas on x-rays indicating gaps between the device and the bone tissue. These indicate a "poor seating" of the plate, showing that it's not staying where intended and is coming loose.

20. Loosening of the Tibial Plate implanted during a total knee replacement or partial knee replacement can be extremely painful. Patients who experience loosening may have trouble walking and usually require additional surgery to remove and replace the loose tibial plate.

21. The Zimmer Persona Knee system was recalled by Zimmer on January 28, 2015. On February 16, 2015 Zimmer issued an "Urgent Medical Device Recall Notice" to distributors, hospitals and surgeons regarding the uncemented Zimmer Persona Trabecular Metal Tibial

Baseplates. Zimmer asked customers to review the notification and ensure personnel are aware of the contents. Zimmer additionally requested that all affected products be located and quarantined.

22. On March 3, 2015 Zimmer issued an “Urgent Medical Device Recall Notice” to hospital risk managers and surgeons. Zimmer said that the current complaint rate for radiolucent lines and loosening is higher than Zimmer’s expectations and experience based on Zimmer’s similar devices. At this time, the complaint rate was 0.61% or 6 complaints per 1,000 devices. Out of the complaints received, 36% identified symptomatic radiolucent lines or were revised for loosening, 28% identified asymptomatic radiolucencies, 8% subsided, and 28% were inconclusive.

23. On March 12, 2015 Zimmer voluntarily recalled the Persona Trabecular Metal Tibial plate that is porous coated and uncemented. The recall affected all lots and sizes C-J Left and Right.

24. The FDA then classified the Persona recall as a Class II recall on March 12, 2015. The recall included nearly 11,700 Persona Tibial plates in all sizes and lots which had been sold to hospitals world-wide from November 29, 2012 through January 23, 2015. Surgeons were warned to no longer use the devices.

25. The FDA noted that all sizes and lots of the affected component were being removed from distribution.

PLAINTIFF SPECIFIC BACKGROUND

26. Plaintiff Laura Woodfield was implanted with a Zimmer Persona trabecular metal tibial base plate device on her left knee, as a part of a Zimmer Persona knee replacement, on April 14, 2014 by Dr. Charles J. Bleifeld.

27. On or about September 2, 2014, Plaintiff underwent a second revision surgery of the Persona device with Dr. Bleifield.

28. The Zimmer Persona trabecular metal tibial base plate device failed and was subsequently recalled after a Class 2 Recall by the FDA on March 12, 2015. (United States Food and Drug Administration, Recall Z-1266-2015.)

29. In 2015, Plaintiff learned that her device was subject to the recall.

30. Plaintiff suffered personal and economic injuries as a result of the implantation of the Zimmer Personal Knee device.

31. Plaintiff suffered personal and economic injuries within the State of New York.

32. Plaintiff has suffered injuries as a result of implantation and revision of the Zimmer Persona Knee device manufactured by defendants.

33. The Zimmer Defendants, by their actions or inactions, proximately caused Plaintiff's injuries.

34. Plaintiff claims damages as a result of injury to herself, including economic loss, diminished earning capacity, past, present, and future pain and suffering, including, but not limited to, chronic and severe pain and limited locomotion, from the permanent injuries caused by the defective Persona knee device.

35. As a result of the failed medical Device, the revised knee implant is not functioning at its full potential, due to the loss of bone cartilage, surface and tissue from the original defective Persona device.

36. Neither Plaintiff nor her physicians, through the exercise of reasonable diligence, could have detected the defective nature of the Zimmer Persona Knee device any earlier than the

evidence of loosening and/or other indication for planned revision of the defective device(s), or as the facts dictate and produced in discovery.

37. As a result of the injuries Plaintiff sustained, she is entitled to recover compensatory damages for pain and suffering and emotional distress and for economic loss as well as punitive damages.

COUNT I
STRICT LIABILITY - DESIGN DEFECT

38. At all relevant times hereto, the Zimmer Defendants were engaged in the development, testing, manufacturing, marketing and sales of the Zimmer Persona Knee.

39. The Zimmer Defendants designed, manufactured, marketed, and sold the Zimmer Persona Knee to medical professionals and their patients, knowing they would be implanted for knee replacements.

40. The Zimmer Persona Knee was designed, manufactured, marketed and sold by Defendants, reached Plaintiff without substantial change in its condition and was used by Plaintiff and Plaintiff's physicians in a reasonably foreseeable and intended manner.

41. The Zimmer Persona Knee was "defective" and "unreasonably dangerous" when it entered the stream of commerce and was received by Plaintiff, because it was dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

42. At no time did Plaintiff have reason to believe that Zimmer Persona Knee was in a condition not suitable for their proper and intended use among patients.

43. The Zimmer Persona Knee was used in the manner for which it was intended, that is, for artificial knee replacement. This use resulted in injury to Plaintiff.

44. The Zimmer Persona Knee was defective, due to defective design rendering the system unsafe.

45. The Zimmer Persona Knee was not reasonably safe due to defective design, because the foreseeable risks of harm posed by the device were sufficiently greater than its foreseeable therapeutic benefits, such that reasonable healthcare providers, knowing of such foreseeable risks and lack of therapeutic benefits, would not prescribe the device for any class of patients.

46. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable care, the defective nature of the Zimmer Persona Knee. Further, in no way could Plaintiff have known that Defendants had designed, developed, and manufactured the Zimmer Persona Knee in such a way as to make the risk of harm or injury outweigh any therapeutic benefits.

47. The Zimmer Persona Knee is defective in design because of its propensity to loosen, specifically, the Persona's porous coated, uncemented trabecular metal tibial plate which was the focus of the class II recall was more likely to loosen, and cause patients unnecessary pain and repeat surgical procedures requiring revision resulting in additional bone loss.

48. The Zimmer Persona Knee is defective in design because of the increased risk for radiolucent lines, loosening and ultimately device failure stemming from the porous coated, uncemented trabecular metal tibial plate. The Persona is also defective in design because the risk of revision surgery is unreasonably greater than other knee implants. The Zimmer Persona Knee offers no clinical benefit over the traditional knee replacement device or devices that feature the standard tibial plate/tibial component that involves cementing or an appropriate stability attachment to the tibia bone.

49. The design of the Persona Knee was flawed in that while it was theoretically designed to remain in place once implanted in the patient, but in practice, its design would actually cause the tibial plate to loosen and or dislodge, causing injury.

50. The Persona Knee was designed in a manner presenting:

- i. An unreasonable risk of loosening due to the design allowing the tibial plate to be used without cementing the plate to the tibia bone;
- ii. An unreasonable risk of radiolucent lines, which evidence poor placement and are an early warning sign of loosening and failure;
- iii. Insufficient structural integrity and design to withstand normal, foreseeable placement within the human body;

51. The Zimmer Persona Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the propensity of the Persona's porous coated, uncemented trabecular metal tibial plate to loosen and cause serious pain and necessitate additional surgery; the postmarketing experience of higher rates of loosening and revision surgery with the Zimmer Persona Knee; and the probability of suffering loosening, pain and revision surgery.

52. The Zimmer Defendants failed to develop and make available alternative products that were designed in a safe or safer manner, or provide a safer tibial plate with cementing to the Persona device, even though such products were feasible and marketable at the time Defendants sold Zimmer Persona Knee to Plaintiff.

53. The Zimmer Persona Knee is unreasonably dangerous because it was sold to Plaintiff without adequate warnings regarding, inter alia, the increased risk of failure of Zimmer

Persona Knee resulting in revision surgery which is unreasonably greater than other knee implants and safer tibial plate components.

54. Defendants had knowledge and information confirming the defective and dangerous nature of the Zimmer Persona Knee.

55. Despite this knowledge and information, Defendants failed to adequately and sufficiently warn Plaintiff and their physicians that Zimmer Persona Knee causes serious permanent injuries including, high failure rate, loosening of the implant, bone loss, decreased range of motion, diminished mobility, and revision surgery.

56. As a direct and proximate result of Defendants' wrongful conduct, including the defective and dangerous design and inadequate warnings of the Zimmer Persona Knee, Plaintiff has sustained and will continue to sustain severe and debilitating injuries, economic loss, and other damages including, but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

COUNT II
STRICT LIABILITY - FAILURE TO WARN

57. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows.

58. The Zimmer Defendants researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold, and otherwise released into the stream of commerce the Zimmer Persona Knee, in the course of same, directly advertised or marketed the product to the FDA, health care professionals, and consumers, including the Plaintiff, or

persons responsible for consumers, and therefore had a duty to warn of the risks associated with the use of the Zimmer Persona Knee.

59. The Zimmer Defendants failed to adequately warn health care professionals and the public, including Plaintiff and her prescribing physician, of the true risks of the Zimmer Persona Knee, including that the Zimmer Persona Knee could loosen, causing severe pain and injury, and requiring further treatment, including revision surgery and/or knee replacement.

60. The Zimmer Defendants failed to timely and reasonably warn of material facts regarding the safety and efficacy of the Zimmer Persona Knee. Had they done so, proper warnings would have been heeded and no health care professional, including Plaintiff's physicians, would have used the Zimmer Persona Knee, or no consumer, including Plaintiff, would have purchased and/or used the Zimmer Persona Knee.

61. Defendants failed to timely and reasonably provide adequate instructions and training concerning safe and effective use of the Zimmer Persona Knee. Had they done so, healthcare professionals, including Plaintiff's physician, could have safely and effectively implanted the Zimmer Persona Knee, without causing serious pain and injury to patients, including Plaintiff.

62. The Zimmer Persona Knee, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction because, after Defendants knew or should have known that there was reasonable evidence of an association between the Zimmer Persona Knee and implant loosening causing serious injury and pain, Defendants failed to provide adequate warnings to health care

professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer Persona Knee.

63. The Zimmer Persona Knee, which was researched, developed, designed, tested, manufactured, inspected, labeled, distributed, marketed, promoted, sold and otherwise released into the stream of commerce by Defendants, was defective due to inadequate post-marketing warnings and/or instruction regarding the increased risk of failure of the Zimmer Persona Knee resulting in revision surgery while knowing that a safer alternative design including the traditional total knee replacements that featured cemented tibial plates existed.

64. Defendants failed to provide adequate warnings to health care professionals and the consuming public, including Plaintiff, and continued to aggressively promote the Zimmer Persona Knee, even though it provides no clinical benefits over other knee replacement systems such as the traditional LPS knee, CR knee and standard tibial components, and had a higher failure rate than the traditional LPS knee, CR knee and standard tibial components.

65. Defendants failed to perform or otherwise facilitate adequate testing; failed to reveal and/or concealed testing and research data; and selectively and misleadingly revealed and/or analyzed testing and research data.

66. As a direct and proximate result of the conduct of Defendants as aforesaid, Plaintiff suffered serious and permanent non-economic and economic injuries.

67. The Zimmer Defendants' conduct, as described above, was reckless. Defendants risked the lives of consumers and users of their products, including Plaintiff, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting consuming public. Defendants' reckless conduct warrants an award of punitive damages.

COUNT III
STRICT LIABILITY - MANUFACTURING DEFECT

68. Plaintiff incorporate by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

69. The Zimmer Defendants designed, developed, manufactured, tested, packaged, advertised, promoted, marketed, distributed, labeled and/or sold the Zimmer Persona Knee, in a condition which rendered them unreasonably dangerous due to its propensity to result in early failure of the device. The subject product was unreasonably dangerous in construction or composition.

70. The Zimmer Persona Knee manufactured and/or supplied by Defendants was defective in manufacture, construction or composition in that, when it left the hands of Defendants, it deviated in a material way from Defendants' manufacturing performance standards and/or it differed from otherwise identical products manufactured to the same design formula.

71. The Zimmer Defendants knew or should have known that the Zimmer Persona Knee could fail early in patients therefore giving rise to pain and suffering, debilitation and the need for revision surgery to replace the device with the attendant risks of complications and death from such further surgery, Defendants continued to market the Zimmer Persona Knee as a safe and effective knee replacement system.

72. Based on information and belief, the manufacturing process employed by Defendants for their Zimmer Persona device, including the Persona Knee implanted in Plaintiff, increased the risk of radiolucent lines and loosening. Based on information and belief, Defendants maintained design and manufacturing specifications that the device's tibial plates were required to have the appropriate metal content, strength, size, durability, appearance,

resistance levels, and should not be subject to radiolucent lines, poor seating, and loosening. The manufacturing process was intended to catch and identify any end-product Persona devices that did not meet specifications and not distribute said devices.

73. As a direct and proximate result of the use of the subject product as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendant, Plaintiff suffered harm, damages and economic loss as previously described and will continue to suffer such harm, damages and economic loss in the future.

COUNT IV
NEGLIGENCE

74. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

75. The Zimmer Defendants was negligent with respect to the designing, manufacturing, testing, inspecting, distributing, and selling of the Zimmer Persona trabecular metal tibial baseplate device.

76. At all times relevant hereto, The Zimmer Defendants had a duty to protect the Plaintiff from the injury that is the basis of this Complaint.

77. The Zimmer Defendants failed to perform that duty, and injury and damages to the Plaintiff was proximately cause by such failure.

78. The Zimmer Defendants failed to warn the Plaintiff of the information that it had in its possession, custody and control regarding the functionality and defectiveness of its product prior to the Zimmer device being distributed within the State of New York and prior to the defective component's installation in the Plaintiff.

79. The Zimmer Defendants breached their duty of care by:

- i. Failing to use due care in the development, design, formulation, manufacturing, labeling, testing, assembly, marketing, advertising,

promotion, inspection, sale and/or distribution of the Zimmer Persona Knee, and/or to utilize and/or implement reasonably safe designs for them;

- ii. Failed to require cementing for all Zimmer Persona tibial plates;
- iii. Failing to provide adequate and proper warnings to the public and to Plaintiff of the dangerous propensities of Zimmer Persona Knee when used in a reasonably foreseeable manner;
- iv. Failed to conduct adequate post marketing surveillance.
- v. Failing to design, formulate, manufacture and incorporate or to reformulate the Zimmer Persona Knee with reasonable safeguards and protections against the type of injury and damage suffered by Plaintiff when used in a reasonably foreseeable manner;
- vi. Failing to adequately prevent, identify, mitigate, and fix defective designs and hazards associated with the Zimmer Persona Knee in accordance with good design practices;
- vii. Failing to notify and warn the public including Plaintiff of reported incidents involving injury, etc., and the negative health effects attendant to the use of the Zimmer Persona Knee, thus misrepresenting the safety of the product;
- viii. Failing to make timely and adequate corrections to the manufacture, design and formulation of Zimmer Persona Knee so as to prevent and/or minimize the problems suffered by Zimmer Persona Knee use;
- ix. Failing to use due care in training and informing health care providers on proper surgical technique and limitations of the device so as to avoid injuries and premature device failure;
- x. Failing to use due care in the testing, formulation, inspection, distribution, sale and instructions regarding the product at all times prior to Plaintiff' injuries having manifested themselves;
- xi. Despite its knowledge of these risks, Defendant continued to promote and market the device; and,
- xii. Being otherwise being careless, reckless and negligent.

80. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale,

labeling, warnings and distribution of the Zimmer Persona Knee and, Plaintiff was implanted with the Zimmer Persona Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she are entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

81. As the direct and proximate result of Zimmer US, Inc.'s negligence, the Plaintiff sustained severe and permanent physical injury, suffered and continues to suffer great pain of body and anguish of mind, required extensive hospital care and treatment, incurred medical expenses, lost time from work, loss of value to pension; Ms. Woodfield required a revision surgery and continues to experience issues with her second knee revision due to the failed first knee revision; and her ability to engage in normal and usual activities has been adversely affected.

WHEREFORE, plaintiff, Laura Woodfield, demands judgment against defendant The Zimmer Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT V
NEGLIGENT MISREPRESENTATION

82. Plaintiff incorporates by reference each and every paragraph of this Amended Complaint as if fully set forth herein and further alleges as follows.

83. Prior to the Plaintiff receiving the Zimmer Persona, Defendants misrepresented that the Zimmer Persona was a safe and effective total knee replacement system.

84. Defendants failed to disclose material facts regarding the safety and efficacy of the Zimmer Persona, including information regarding increased risk of loosening and failure, harmful side-effects, increased risk of revision surgery due to the uncemented tibial plate, with little to no clinical benefit over standard tibial components.

85. Defendants had a duty to provide Plaintiff, physicians and other consumers with true and accurate information and warnings of any known risks and harmful side effects of the medical device they marketed, distributed and sold.

86. Defendants knew or should have known, based on prior experience, adverse event reports, studies and knowledge of the efficacy and safety failures associated with the Zimmer Persona that their representations regarding the Zimmer Persona were false, and that they had a duty to disclose the dangers associated with the device.

87. Defendants made the representations and failed to disclose the material facts with the intent to induce consumers, including the Plaintiff, and the medical community to act in reliance by purchasing the Zimmer Persona.

88. Plaintiff and the medical community justifiably relied on Defendants representations and nondisclosures by purchasing and using the Zimmer Persona.

89. Defendants' representations and nondisclosures regarding the safety and efficacy of the Zimmer Persona was the direct and proximate cause of Plaintiff's injuries.

WHEREFORE, plaintiff, Laura Woodfield, demands judgment against the Zimmer Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT VI
BREACH OF EXPRESS WARRANTY

90. Plaintiff incorporates by reference each and every paragraph of this Complaint as if fully set forth herein and further alleges as follows:

91. The Zimmer Defendants advertised, labeled, marketed and promoted the Zimmer Persona Knee, representing the quality to health care professionals, the FDA, Plaintiff, and the public in such a way as to induce its purchase or use, such as:

- i. indicating that the Persona device was the “personalized knee system” which was “designed to minimize the compromises experienced with yesterday’s standard knee systems”
- ii. And that the Persona device offered “unparalleled levels of personalization, empowering surgeons to restore the unique identity of every knee.”

92. These assertions made an express warranty that the Zimmer Persona Knee would conform to the representations.

93. More specifically, Zimmer Defendants represented that the Zimmer Persona Knee was safe and effective, that it was safe and effective for use by individuals such as Plaintiff, and/or that it was safe and effective to treat Plaintiff’s condition.

94. The representations, as set forth above, contained or constituted affirmations of fact or promises made by the seller to the buyer which related to the goods and became part of the basis of the bargain creating an express warranty that the goods shall conform to the affirmations of fact or promises.

95. The Zimmer Persona Knee did not conform to the representations made by Defendants in that the Zimmer Persona Knee was not safe and effective, was not safe and

effective for use by individuals such as Plaintiff, and/or was not safe and effective to treat in individuals, such as Plaintiff.

96. At all relevant times, Plaintiff used the Zimmer Persona Knee for the purpose and in the manner, which was reasonably foreseeable to Defendants.

97. Plaintiff and Plaintiff's physicians, by the use of reasonable care, could not have discovered the breached warranty and realized its danger.

98. The breach of the warranty was a substantial factor in bringing about Plaintiff injuries.

99. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer Persona Knee, Plaintiff was implanted with Zimmer Persona Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, plaintiff, Laura Woodfield, demands judgment against Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT VII
BREACH OF IMPLIED WARRANTY

100. Plaintiff repeats and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

101. The Zimmer Persona Knee was not reasonably fit for the ordinary purposes for which such goods are used and did not meet the expectations for the performance of the product

when used in the customary, usual and reasonably foreseeable manner. Nor was the Zimmer Persona Knee minimally safe for its expected purpose.

102. At all relevant times, Plaintiff used the Zimmer Persona Knee for the purpose and in the manner intended by Defendants.

103. Defendants sold the Persona device for plaintiff's ultimate use.

104. Plaintiff and Plaintiff's physicians, by the use of reasonable care could not have discovered the breached warranty and realized its danger.

105. Defendants impliedly warranted to Plaintiff and her physicians that the Persona device was safe and of merchantable quality and for the ordinary purpose for which the product was intended and marketed to be used.

106. The alleged defects existed at the time the Persona device left the Zimmer Defendant's possession.

107. The representations and implied warranties made by Defendants were false, misleading, and inaccurate because the Persona device was defective, unsafe, unreasonably dangerous, and not of merchantable quality, when used as they were marketed and intended to be used. Specifically, at the time Plaintiff and her physicians purchased and used the devices, the products were not in a merchantable condition in that:

- a. The Persona device offered no benefit to patient outcomes,
- b. The Persona device suffered from unreasonably high loosening and revision rates.

108. The breach of the warranty was a substantial factor in bringing about Plaintiff injuries.

109. As a direct and proximate result of Defendants' acts and omissions, including their failure to exercise ordinary care in the design, formulation, testing, manufacture, sale, and distribution of Zimmer Persona Knee, Plaintiff was implanted with Zimmer Persona Knee and suffered severe and debilitating injuries, economic loss, and other damages, including but not limited to, cost of medical care, rehabilitation, lost income, permanent instability and loss of balance, immobility, and pain and suffering, for which she is entitled to compensatory and equitable damages and declaratory relief in an amount to be proven at trial.

WHEREFORE, plaintiff, Laura Woodfield, demands judgment against Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

COUNT VII
VIOLATIONS OF CONSUMER PROTECTION STATUTES
New York Consolidated Laws Service General Business § 349, 350-e

110. Plaintiff repeats and incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

111. The Defendants acted, used, and employed unconscionable commercial practices, deception, fraud, false pretenses, false promises, and misrepresentations and knowingly concealed, suppressed, and omitted material facts with the intent that consumers, including Plaintiff's physicians and medical providers, relied upon such concealment, suppression, and omission in connection with sale, advertisement, and promotion of the Persona, in violation of all applicable state consumer fraud statutes, for the purpose of influencing and inducing physicians and medical providers to prescribe the Persona knee to patients/consumers, such as Plaintiff.

112. By reason of Defendants' unconscionable, deceptive, and fraudulent acts and practices, false pretenses, false promises, and misrepresentations, reasonable patients/consumers acting reasonably, such as Plaintiff, were caused to suffer ascertainable loss of money, property, and actual damages.

113. Defendants engaged in consumer-oriented, commercial conduct by selling and advertising the subject Persona knee devices.

114. Defendants misrepresented and omitted material information regarding the subject product by failing to disclose known risks.

115. Defendants' misrepresentations and concealment of material facts constitute unconscionable commercial practices, deception, fraud, false pretenses, misrepresentation, and/or knowing concealment, suppression, or omission of materials facts with the intent that others rely on such concealment, suppression, or omission in connection with the sale and advertisement of the subject product, in violation of New York General Business Law ("GBL") §§ 349, 350.

116. New York has enacted statutes to protect consumers from deceptive, fraudulent, and unconscionable trade and business practices. Defendants violated these statutes by knowingly and falsely representing that the subject Persona knee devices were fit to be used for their intended purpose when Defendants knew it was defective and dangerous and by other acts alleged herein.

117. Defendants engaged in the materially deceptive and misleading acts and practices alleged herein in order to sell the subject knee devices to the public, including Plaintiff.

118. Plaintiff relied upon Defendant's practices.

119. As a direct and proximate result of Defendants' violations of GBL §§ 349 and 350, Plaintiff suffered damages that entitle Plaintiff to compensatory damages, equitable and declaratory relief, punitive damages, costs, and reasonable attorneys' fees.

120. As a direct and proximate result of Defendants' conduct, Plaintiff used the Persona device implanted in her and suffered serious physical injury, harm, damages, and economic loss and will continue to suffer such harm, economic loss, and damages.

121. The Defendant's actions were unfair and deceptive within the meaning of NY CLS Gen Bus § 349.

WHEREFORE, plaintiff, Laura Woodfield, demands judgment against Defendants in such amount that the court may deem just and proper, plus interest, costs, and attorney's fees in such amount as that which the plaintiff may be entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against the Defendants on each of the above-referenced claims and Causes of Action and as follows:

1. Awarding compensatory damages in excess of the jurisdictional amount, including, but not limited to pain, suffering, emotional distress, loss of enjoyment of life, and other non-economic damages available by law or statute in an amount to be determined at trial of this action;
2. Awarding economic damages in the form of medical expenses, out of pocket expenses, lost earnings and other economic damages paid or owed by Plaintiff in an amount to be determined at trial of this action;
3. Punitive and/or exemplary damages for the wanton, willful, fraudulent, reckless acts of the Defendants, which constitute gross negligent, as Defendants demonstrated a complete disregard and reckless indifference for the safety and welfare of the general public and to the Plaintiff in an amount sufficient to punish Defendants and deter future similar conduct;
4. Prejudgment interest;
5. Post-judgment interest;

6. Awarding Plaintiff the costs of these proceedings; and
Such other and further relief as this Court deems just and proper.

JURY DEMAND

Plaintiff hereby demand a trial by jury as to all claims in this action.

Dated: August 11, 2017

Napoli Shkolnik, LLC

By: /s/ Nicholas R. Farnolo
Nicholas R. Farnolo (NF 6598)
400 Broadhollow Road
Melville, NY 11747
(212) 397-1000
Nfarnolo@NapoliLaw.com
Attorney for Plaintiff

CIVIL COVER SHEET

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

I. (a) PLAINTIFFS

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

(c) Attorneys (Firm Name, Address, and Telephone Number)

DEFENDANTS

County of Residence of First Listed Defendant (IN U.S. PLAINTIFF CASES ONLY)

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

Attorneys (If Known)

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

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

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- Citizen of This State, Citizen of Another State, Citizen or Subject of a Foreign Country, PTF DEF, Incorporated or Principal Place of Business In This State, Incorporated and Principal Place of Business In Another State, Foreign Nation

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

Click here for: Nature of Suit Code Descriptions.

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

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 - Transfer, 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity): Brief description of cause:

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 SIGNATURE OF ATTORNEY OF RECORD

FOR OFFICE USE ONLY

RECEIPT # AMOUNT APPLYING IFP JUDGE MAG. JUDGE

CERTIFICATION OF ARBITRATION ELIGIBILITY

Local Arbitration Rule 83.10 provides that with certain exceptions, actions seeking money damages only in an amount not in excess of \$150,000, exclusive of interest and costs, are eligible for compulsory arbitration. The amount of damages is presumed to be below the threshold amount unless a certification to the contrary is filed.

I, _____, counsel for _____, do hereby certify that the above captioned civil action is ineligible for compulsory arbitration for the following reason(s):

monetary damages sought are in excess of \$150,000, exclusive of interest and costs,

the complaint seeks injunctive relief,

the matter is otherwise ineligible for the following reason

DISCLOSURE STATEMENT - FEDERAL RULES CIVIL PROCEDURE 7.1

Identify any parent corporation and any publicly held corporation that owns 10% or more of its stocks:

RELATED CASE STATEMENT (Section VIII on the Front of this Form)

Please list all cases that are arguably related pursuant to Division of Business Rule 50.3.1 in Section VIII on the front of this form. Rule 50.3.1 (a) provides that "A civil case is "related" to another civil case for purposes of this guideline when, because of the similarity of facts and legal issues or because the cases arise from the same transactions or events, a substantial saving of judicial resources is likely to result from assigning both cases to the same judge and magistrate judge." Rule 50.3.1 (b) provides that " A civil case shall not be deemed "related" to another civil case merely because the civil case: (A) involves identical legal issues, or (B) involves the same parties." Rule 50.3.1 (c) further provides that "Presumptively, and subject to the power of a judge to determine otherwise pursuant to paragraph (d), civil cases shall not be deemed to be "related" unless both cases are still pending before the court."

NY-E DIVISION OF BUSINESS RULE 50.1(d)(2)

- 1.) Is the civil action being filed in the Eastern District removed from a New York State Court located in Nassau or Suffolk County: _____
- 2.) If you answered "no" above:
 - a) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in Nassau or Suffolk County? _____
 - b) Did the events or omissions giving rise to the claim or claims, or a substantial part thereof, occur in the Eastern District? _____

If your answer to question 2 (b) is "No," does the defendant (or a majority of the defendants, if there is more than one) reside in Nassau or Suffolk County, or, in an interpleader action, does the claimant (or a majority of the claimants, if there is more than one) reside in Nassau or Suffolk County? _____

(Note: A corporation shall be considered a resident of the County in which it has the most significant contacts).

BAR ADMISSION

I am currently admitted in the Eastern District of New York and currently a member in good standing of the bar of this court.

Yes No

Are you currently the subject of any disciplinary action (s) in this or any other state or federal court?

Yes (If yes, please explain) No

I certify the accuracy of all information provided above.

Signature: _____

Civil Action No. _____

PROOF OF SERVICE

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

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

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

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

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

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

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

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

Civil Action No. _____

PROOF OF SERVICE

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

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_____ on *(date)* _____ ; or

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

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

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

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

_____ District of _____

Plaintiff(s)

v.

Defendant(s)

)
)
)
)
)
)
)
)
)
)
)
)

Civil Action No. _____

SUMMONS IN A CIVIL ACTION

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

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:

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

CLERK OF COURT

Date: _____

Signature of Clerk or Deputy Clerk

Civil Action No. _____

PROOF OF SERVICE

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

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

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

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

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

I returned the summons unexecuted because _____ ; or

Other *(specify)*: _____ .

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

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

Date: _____

Server's signature

Printed name and title

Server's address

Additional information regarding attempted service, etc: