IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Civil Action No.: 1:19-cv-1515

Regina Dibala,

Plaintiff,

v.

DePuy Orthopaedics, Inc., an Indiana Corporation and
Medical Device Business Services, Inc.,
an Indiana Corporation.

Defendants.

COMPLAINT AND JURY DEMAND

Regina Dibala (hereinafter "Plaintiff" or "Mrs. Dibala"), through her attorneys, BAITY & LINDVIG, LLC, hereby submits the following Complaint and Jury Demand against DePuy Orthopedics, Inc. now known as Medical Device Business Services, Inc., and states as follow:

THE PARTIES & JURISDICTION

1. Mrs. Dibala is and at all times relevant to this action a citizen and resident of the State of Colorado, residing in Jefferson County, Colorado.

2. DePuy Orthopaedics, Inc. ("DePuy") was and at all times relevant a corporation organized and existing under the laws of the State of Indiana, with its headquarters and principal place of business at 700 Orthopaedic Drive, Warsaw, Indiana, 46581, and duly licensed and authorized to conduct business within the state of Colorado. Its Registered Agent is The Corporation Company, 7700 E. Arapahoe Rd., Ste. 220, Centennial, Colorado 80112. At all relevant times, Defendant DePuy Orthopaedics, Inc. regularly conducted business in Colorado

3. In March, 2017, DePuy changed its entity name to Medical Device Business Services, Inc. ("MDBS").

4. Defendant Medical Device Business Services, Inc., is an Indiana corporation with its principal place of business located at 700 Orthopaedic Drive, Warsaw, Indiana 46582, which is located in Kosciusko County. At all relevant times, Defendant Medical Device Business Services regularly conducted business in Colorado.

5. At all times relevant, Defendants were the representatives, agents, employees, coconspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

6. Each Defendant was involved in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third parties or related entities, numerous orthopedic products, including the DePuy ATTUNE Knee System, as well as monitoring and reporting adverse events.

7. This Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332, because the amount in controversy exceeds $75,000.00, exclusive of interest and costs, and because Defendants are incorporated and have their principal places of business in states other than the state in which Plaintiff resides.

8. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because a substantial part of the events giving rise to Plaintiff's claims occurred, in part, in this District, and because Defendants conducted regular business in this District.

9. Plaintiff resides in Arapahoe County, Colorado which is in the United States District Court for Colorado.

GENERAL ALLEGATIONS

10. The knee is the largest joint in the human body, consisting of three individual bones: the shin bone (tibia), the thigh bone (femur), and the knee-cap (patella). The knee joint is lined with cartilage to protect the bones from rubbing against each other. This ensures that the joint surfaces can glide easily over one another. The human knee is a complicated joint which supports the entire body weight on four surfaces through a variety of motions essential to everyday life.

11. People who suffer pain and disability from injury or damage to the knee joint may elect to have a knee replacement. Knee replacement technology can provide a solution to the pain and restore basic function. Total knee arthroplasty ("TKA"), also called total knee replacement ("TKR"), is a commonly performed orthopedic procedure. The surgery is designed to help relieve pain, to improve joint function, and to replace bones, cartilage and/or tissue that have been severely injured and/or worn down generally in people with severe knee degeneration due to arthritis, other disease or trauma.

HISTORY OF DEPUY KNEES AND THE ATTUNE SYSTEM

12. Defendants represented that the DePuy AttuneTM Knee System "builds on the LCS Complete Knee System and the Sigma Rotating Platform Knee" both of which are also Defendants' products.

13. Defendants introduced the DePuy Synthes P.F.C. SIGMA System ("SIGMA system") in 1996.

14. The SIGMA system was one of the most widely used TKAs worldwide, and Defendants quickly became one of the largest manufacturers of knee replacement devices in the

United States. According to Defendants, the SIGMA system has demonstrated excellent survivorship with 99.6% at 7 years.

15. Notwithstanding Defendants' alleged success with the SIGMA system, as reported by DePuy, the company began to alter the SIGMA system design in an effort to replicate the total flexion of the natural knee and maintain a competitive position in the market. This new project—one that Defendants boasted as their largest research and development project ever, carrying a price tag of approximately $200 million—resulted in the DePuy AttuneTM Knee System, ("ATTUNE system").

16. According to Defendants, the new ATTUNE system was an attempt to improve functional outcomes, provide more stability and simplify implantation of the contemporary total knee system.

17. Defendants represented the ATTUNE system featured a gradually reducing femoral radius, an innovative s-curve design of the posteriorly stabilized cam, a tibial base which can be downsized or upsized two sizes versus the insert, novel patella tracking, lighter innovative instruments, and a new polyethylene formulation.

18. Defendants sought FDA clearance for the ATTUNE system through the "510(k)" process.

19. Section 510(k) of the Food, Drug and Cosmetic Act provides a mechanism for device manufacturers to obtain accelerated FDA clearance for products that are shown to be "substantially equivalent" to a product that has previously received FDA approval. The process requires device manufacturers to notify the FDA of their intent to market a medical device at least 90 days in advance of introduction to the market. This is known as Premarket Notification – also

called PMN or 510(k). This approval process allows the FDA to determine whether the device is substantially equivalent to a device already approved for marketing.

20. In December 2010, Defendants received FDA clearance of the ATTUNE System under the "510k" notification process. The basis for FDA clearance was substantial similarity to several prior devices, including, but not limited to, the P.F.C. SIGMA Knee System. Consequently, Defendants received FDA 510(k) approval of the components of the ATTUNE system in 2010 and 2011 with very limited testing of the new ATTUNE system.

21. The ATTUNE system includes the Attune Tibial Base (510K Number K101433), also called the tibial tray, which, as compared to the SIGMA system, included a design change to the keel, the surface texture and/or finish of the tibial baseplate and "combined with new technology to treat the underside of the implant," among other changes.

22. The design and composition of the ATTUNE system, especially the tibial baseplate, is defective and failed resulting in harm to Regina Dibala.

23. In March 2013, Defendants introduced its ATTUNE system, including procedures for implantation, to surgeons and consumers. On March 20, 2013, Defendants issued a press release widely introducing its "latest innovation in total knee replacement—the ATTUNE Knee System—at the 2013 American Academy of Orthopedic Surgeons (AAOS) annual meeting in Chicago."

24. According to the Press release, the ATTUNE system was "designed to provide better range of motion and address the unstable feeling some patients experience during everyday activities, such as stair descent and bending." According to Defendants, its "proprietary technologies include: … SOFCAMTM Contact: An S-curve design that provides a smooth engagement for stability through flexion, while reducing stresses placed on the implant."

25. Defendants claimed the Attune system contained "new" technologies and that the Attune system was one of the largest research and development projects in the history of the DePuy Synthes Companies, costing approximately $200 million. Defendants claimed the following features of the ATTUNE system: "the largest clinical program at DePuy," "improves value of TKA," "compares favorably in joint registries," and "significantly less symptomatic crepitus, primarily Sigma PS."

26. The most notable improvement Defendants purported to make between the SIGMA and ATTUNE system is the patented S-curve design of the femoral component. This feature, according to Defendants conferred greater mid flexion stability as the implanted knee moves from extension to flexion because of the more gradual change in the femoral component radius of curvature. This design feature was also proposed to offer greater functional benefits and a greater range of movement as compared to other implants.

27. However, the ATTUNE system did not deliver on these promises, resulting in significantly higher failure rates than previous Defendant knee counterparts due to the debonding of the tibial baseplate. As a result, thousands of knee replacement patients implanted with ATTUNE systems have had more expensive, more dangerous and less effective total knee replacement surgeries, and many have required or will require expensive and dangerous knee revision surgery to remove and replace the defective ATTUNE system.

28. Since the initial launch, Defendants have continued to expand the ATTUNE system product line based on claims it would provide a more life-like knee to patients who were "expecting to maintain an active lifestyle." Defendants have successfully marketed the ATTUNE system and have become the dominant player in the knee market, upon information and belief, selling approximately 400,000 ATTUNE systems worldwide.

FAILURES OF THE ATTUNE SYSTEM

29. The primary reason the ATTUNE system fails is mechanical loosening. The mechanical loosening is caused by a failure of the bond between the tibial baseplate at the implant cement interface. The attachment between the artificial knee and the existing bone becomes loose over time and with use. The mechanical loosening eventually results in failure of the device. Mechanical loosening has occurred at an unprecedented rate in patients implanted with an ATTUNE system.

30. Mechanical loosening of an artificial knee can be visualized and diagnosed using radiographic imaging. The loosening can be evident from one or more radiolucent lines around the contours of the artificial knee component where the loosening is occurring.

31. Mechanical loosening in an artificial knee generally causes pain and wearing away of the bone. The patient loses function of the knee which can severely restrict a patient's daily activities.

32. Once there is mechanical loosening, the patient may require a second revision surgery to remove the knee implant and replace it with a new one.

33. A failed total knee prosthesis often causes severe bone loss. Therefore, revision surgeries are often more complicated and the patient has a greater period of recovery.

34. The success rate of a revision surgery is much lower than that of the initial total knee replacement and the risks and complications are higher, including increased pain and limitations in range of motion.

35. Beginning in 2013, Defendants became aware of issues with the ATTUNE system. These concerns were evidenced through failure reports submitted to and kept in the FDA's Manufacturer and User Facility Device Experience (MAUDE), which houses medical device

reports submitted to the FDA by reporters such as manufacturers, importers and device user facilities. Most related reports concern failures caused by ATTUNE system design elements which caused loosening and/or de-bonding at the tibial baseplate cement/implant interface. These MAUDE reports detail a high incidence of aseptic loosening at the tibial baseplate of the ATTUNE system resulting in subsequent revision surgeries.

36. Upon information and belief, the FDA MAUDE database, as of June 2017, includes approximately 1,400 reports of failures. Approximately 633 of these reports resulted in revision surgeries.

37. On March 15, 2017, DePuy Synthes, at the American Academy of Orthopaedic Surgeons ("AAOS") Annual Meeting in San Diego, California, announced the launch of the first ATTUNE Revision Knee System ("ATTUNE Revised system"), which included the Attune Revision Fixed Bearing Tibial Base and a 14 x 50 mm Cemented Stem.

38. Ostensibly, noticing the alarming rate of failure and subsequent revisions related to the ATTUNE system, on March 10, 2016, Defendants submitted a Section 510(k) premarket notice of intent to market the ATTUNE Revised system, which included a new stem, with added length and a keel for additional stability and recessed cement pockets intended to promote cement fixation. The stem of the ATTUNE Revised system was designed with a cylindrical or tapered body geometry with a blasted and fluted fixation surface.

39. Without notifying consumers, doctors or patients, including Plaintiff and her physicians, Defendants recently attempted to replace the original Attune Fixed Base tibial baseplate with a new tibial baseplate, also called a tibial tray, which received FDA 510(k) clearance on June 15, 2017. This strategic decision to design and launch a newly designed tibial baseplate is an admission, or compelling evidence, the original Attune tibial baseplate is defective

and prone to failure. However, Defendants have not recalled the defective tibial baseplate or informed consumers and surgeons about the dangers of its use.

40. Defendants requested FDA approval of the new tibial baseplate by application dated March 17, 2017, which was "prepared" by Defendants on March 16, 2016. The application requested clearance of a new tibial baseplate component as part of the Attune system, which, upon information and belief, has been called the "Attune S+ Technology" ("ATTUNE S+") by Defendants. In particular, the application identified the design changes that were implemented with the ATTUNE S+, including a newly designed "keel to provide additional stability," "recessed undercut cement pockets," and a "grit blasted surface for enhanced cement fixation" or microblast finish.

41. The "Summary of Technologies" portion of the 510(k) application for the ATTUNE S+ tibial baseplate includes the following: The ATTUNE Cemented Tibial Base, FB provides a macro geometric feature and an optimized micro-blast finish which are both intended to aid in fixation of the tibial implant to the bone cement. The ATTUNE Cemented Tibial Base, FB is designed to enhance fixation by improving resistance (relative to the industry) to intra-operative factors which can result in a reduction in cement to implant bond.

42. Additionally, according to Defendants, the ATTUNE S+ tibial baseplate also features macro geometry and 45-degree undercut pockets designed to provide a macro-lock between the cement-implant interface. According to Defendants, the "ATTUNE S+ Technology finishing process increases the surface roughness compared with other, DePuy Synthes clinically proven, tibial tray designs that were tested." See Depuy Synthes Powerpoint, "ATTUNE S+ Technology."

43. Defendants knew about the design defects and resulting failures with the original ATTUNE tibial baseplate before the newly designed tibial baseplate (ATTUNE S+) was cleared in June 2017, yet they failed to share this information with orthopedic surgeons using the ATTUNE systems.

44. By March 16, 2016, Defendants had recognized the existence of high failure rates of the original ATTUNE tibial baseplate, identified the defects and/or mechanisms of failure associated with it, researched and designed the new tibial tray/baseplate (ATTUNE S+), conducted testing of this new tibial baseplate, as detailed in the application, and submitted the application to the FDA.

45. Although Defendants knew about the high number of ATTUNE system failures resulting in revision surgeries, Defendants failed to warn surgeons, consumers and patients, and allowed the original, defective design to continue to be implanted by unsuspecting surgeons into unsuspecting patients.

46. Beginning in December 2016, Defendants began openly admitting, in its responses in the MAUDE failure reports, that the ATTUNE systems were failing. Although Defendants decided to make a change, it did not inform the surgeons, consumers and/or patients. In responding to the MAUDE reports involving failures of ATTUNE tibial baseplates, Defendants frequently provided the following "Manufacturer Narrative": The information received will be retained for potential series investigations if triggered by trend analysis, post market surveillance or other events within the quality system. (b)(4) has been undertaken to investigate further. The analysis and investigations eventually led to a new product development project, which will enhance fixation and make the product more robust to surgical technique per co (b)(4). DePuy

considers the investigation closed at this time. Should the additional information be received, the information will be reviewed and the investigation will be reopened as necessary.

47. In January 2017, the Journal of Arthroplasty published a study, led by Dr. Raymond H. Kim and other surgeons at Colorado Joint Replacement, Department of Orthopedic Surgery, and OrthoCarolina, Department of Orthopaedic Surgery entitled, Tibial Tray Thickness Significantly Increases Medial Tibial Bone Resorption in Cobalt-Chromium Total Knee Arthroplasty Implants. The study reported that the thicker cobalt-chromium baseplate of the ATTUNE system was associated with significantly more tibial bone loss.

48. During the AAOS Annual Meeting in March 2017, Dr. Todd Kelley, Assistant Professor of Orthopaedic Surgery at the University of Cincinnati College of Medicine, presented a poster entitled High Incidence of Stress Shielding and Radiolucent Lines with a Novel Total Knee System, which involved a study of the ATTUNE system.

49. Prior to the study, the evaluators acknowledged that a relationship between stress shielding and bone resorption leading to aseptic loosening and implant failure existed. Consequently, the purpose of the study was to determine the incidence of radiographic stress shielding and radiolucent lines in the tibia and femur during the early postoperative period following the implant of an ATTUNE system.

50. As part of this study, 164 patients underwent a total knee replacement with the ATTUNE system between February 2013 and February 2015. The mean length of the postoperative radiographic follow up was eight months. For all evaluators in the study, stress shielding was most frequently identified at the same three zones, with the highest incidence at "tibial AP zone 1," which was the medial baseplate. The incidence rate at this zone was 39.0%-48.5%.

51. The findings also demonstrated that the mean incidence rate of stress shielding at the tibial AP zone 1 among all evaluators was 43.1% and the mean incidence rate of radiolucent lines observed at this zone was 12.0%. These rates far exceed the rate expected in the post-surgery period.

52. In 2017, the alarming rate of failure associated with the ATTUNE system due to debonding of the tibial baseplate was discussed in a paper written by Dr. Peter M. Bonutti and colleagues, entitled Unusually High Rate of Early Failure of Tibial Component in ATTUNE Total Knee Arthoplasty System at Implant-Cement Interface. The article presented compelling evidence that the design and/or composition of the ATTUNE system, and particularly the tibial baseplate component, contribute greatly to de-bonding at the interface between the cement and the tibial baseplate, resulting in high rates of failure and revision surgery.

53. The authors' intraoperative findings identified freely mobile tibial baseplates with loosening occurring at the implant-cement interface. In all tibial baseplate failures in the study, the tibial component had de-bonded and was easily separated from the cement mantle, while all the cement was strongly adherent to the tibial bone. On the femoral side, however, the cement was strongly adherent to the implant surface in all cases. The mean time to revision for those ATTUNE systems involved in the study was 19 months.

54. The authors of the Bonutti study concluded that high rates of ATTUNE system failures due to de-bonding at the tibial-cement interface could be caused by a combination of factors, including the increased constraint of the ATTUNE's tibial polyethylene component; rounded edges and reduced cement pockets necessary for cement inter-digitation in the tibia, as compared to the DePuy SIGMA; reduced keel rotational flanges and/or stabilizers on the keel; and insufficient surface roughness of the tibial baseplate component.

55. Despite Defendants' claim that the ATTUNE system would be easier to implant, after being notified of premature tibial baseplate failures, Defendants began blaming implanting surgeons and their surgical technique for the failures of the ATTUNE tibial baseplates rather than the ATTUNE system's defects, which Defendants knew existed.

DEFENDANTS' MARKETING OF ATTUNE SYSTEMS

56. According to Defendants, the ATTUNE system produces better stability of the knee in deep flexion, reduces the joint forces, and produces better patella tracking, operative flexibility and efficiency, and implant longevity. Defendants marketed the ATTUNE system based on these assertions. Despite these claims, large numbers of revision cases appeared in a short period resulting from the defects in the ATTUNE tibial baseplate.

57. Defendants promised patients they could recover faster, and engage in more active lifestyles. Contrary to Defendants' representations, however, the ATTUNE system is prone to failure, causing patients to experience additional pain and injury.

58. Defendants designed, manufactured, tested, labeled, packaged, distributed, supplied, marketed, advertised, and/or otherwise engaged in all activities that are part of the sale and distribution of medical devices, and by these activities, caused the ATTUNE systems to be placed into the stream of commerce throughout the United States, including Colorado.

59. Defendants actively and aggressively marketed to doctors and the public that the ATTUNE systems were safe and effective total knee prostheses.

60. From the time that Defendants first began selling the ATTUNE systems, the product labeling and product information for the ATTUNE system failed to contain adequate information, instructions, and warnings concerning the increased risk that the ATTUNE system fails at an extremely high rate.

61. Despite Defendants' knowledge of the serious injuries associated with the use of the ATTUNE system, Defendants continue to engage in marketing and advertising programs which falsely and deceptively create the perception that the ATTUNE system is safe.

62. Upon information and belief, Defendants downplayed the health risks associated with the ATTUNE system through promotional literature and communications with orthopedic surgeons. Defendants deceived doctors, including Plaintiff's surgeon, and potential users of the ATTUNE system by relaying positive information, while concealing the nature and extent of the known adverse and serious health effects of the ATTUNE system.

63. Based on the design changes made to the original Attune tibial baseplate before it was put on the market, and the number of failures reported since it was launched, Defendants, through their premarketing and post-marketing analysis, knew or should have known that the ATTUNE system was prone to fail. Plaintiff the ATTUNE system is defective and unreasonably dangerous.

CASE SPECIFIC FACTUAL ALLEGATIONS

64. On or about April 8, 2013, Plaintiff underwent a surgical procedure by Dr. John S. Xenos, M.D., at the Sky Ridge Medical Center in Lone Tree, Colorado. The surgical procedure was a left total knee arthroplasty. Plaintiff's natural, biological left knee joint was removed and replaced by an artificial knee prosthesis manufactured and marketed by the Defendant and known as the ATTUNE Knee system.

65. In a total knee replacement surgery, physicians resurface the bone at the top of the shin (tibia) with a metal tray topped with a medical-grade plastic spacer, called a bearing. This plastic replaces the cartilage, providing a cushioning surface for the new knee. The bottom of the thigh (femur) bone is resurfaced with a rounded metal part. This piece is designed to mimic the

curve of the natural bone. These components can be fixed to the bone by either using bone cement or a press fi, allowing the bone to grow into the coating on the implant.

66. The Defendant represented that physical therapists noted that ATTUNE Knee System patients had significantly greater range of motion than other knee replacement patients. Defendant represented that the ATTUNE Knee System helps you maintain stability during activities like walking and going up and down stairs.

67. Contrary to these claims, the ATTUNE Knee System was in fact prone to premature failure and dislocation and to cause patients to experience great pain an instability. In addition, the glue used to adhere the parts was known to fail, cause patients to feel a slipping sensation and instability.

68. Within 5 years after the ATTUNE system was implanted, Mrs. Dibala began experiencing severe and persistent pain, discomfort, instability and difficulty ambulating caused by aseptic loosening of the defective ATTUNE tibial baseplate.

69. Mrs. Dibala's physician took and viewed radiographs which showed loosening and debonding of the tibial tray.

70. On December 12, 2018, Mrs. Dibala underwent revision surgery due to loosening of the components of the ATTUNE system implanted in her right knee. This surgery was performed by Dr. John S. Xenos at the Sky Ridge Medical Center in Lone Tree, Colorado. Neither Mrs. Dibala nor her physicians were aware, by warning or otherwise, of the defects in the ATTUNE system, and would not have used the ATTUNE system had they been aware of the defective nature of the device.

71. As a direct and proximate result of Defendants placing the ATTUNE system in the stream of commerce, Mrs. Dibala has suffered and continues to suffer both injuries and damages,

including, but not limited to: past, present and future physical and mental pain and suffering; and past, present and future medical, hospital, rehabilitative, monitoring, and pharmaceutical expenses, economic damages, severe and possibly permanent injuries, and other related damages.

72. All of the injuries and complications suffered by Plaintiff were caused by the defective design, warnings, construction, and unreasonably dangerous character of the ATTUNE system that was implanted in him. Had Defendants not concealed the known defects, the early failure rate, the known complications, and the unreasonable risks associated with the use of the ATTUNE system, Ms. Dibala would not have consented to the ATTUNE system being used in her total knee arthroplasty.

73. The said MDBS product was used for the purpose for which it was designed, intended and marketed and, at the time it failed and injured Ms. Dibala, was not materially changed in any way from the condition it was in when sold by the Defendants.

FIRST CLAIM FOR RELIEF
(Strict Liability)

74. Plaintiff incorporates all other allegations of this complaint as if fully rewritten.

75. Plaintiff suffered injuries, damages, and losses in amounts to be proven at trial.

76. Defendant designed, manufactured, promoted, distributed, marketed, and sold the ATTUNE Knee System that was defective and injured Plaintiff.

77. At all times relevant, Defendants were in the business of selling ATTUNE Knee System for use by and upon consumers.

78. At all times relevant, the ATTUNE Knee system that Plaintiff received was in a defective and unreasonably dangerous condition. Such condition included, but is not limited to, one or more of the following particulars:

a. The ATTUNE Knee system that Plaintiff received contained design defects including but not limited to, mechanical loosening and failures due to de-bonding at the tibial-cement interface: including the increased constraint of the ATTUNE's tibial polyethylene component; rounded edges and reduced cement pockets necessary for cement inter-digitation in the tibia; reduced keel rotational flanges and/or stabilizers on the keel; and insufficient surface roughness of the tibial baseplate component.

i. The ATTUNE Knee system design of the implant subjected Plaintiff and others to risks, including the risk that Plaintiff would develop inflammation, swelling, and bone loss, as a result of the implant, causing the implant to prematurely fail, and requiring Plaintiff to undergo a complex risky, and painful surgery to remove and replace the defective implant.

ii. Safer alternative designs existed, including the design used during Plaintiff's revision surgery.

iii. The likelihood of the ATTUNE Knee system causing injuries of the sort Plaintiff sustained was high, given the significant number of persons who experienced loosening and ultimate failure of the implant.

iv. Neither the ultimate consumer – Plaintiff, in this case – nor her health care providers had the ability to avoid via exercise of reasonable care the consequences that befell Mrs. Dibala in this case because they did not know and had no reason to know of the defects in the implant.

v. As detailed further below, the ATTUNE Knee system lacked any warnings or instructions that might have ameliorated the risks that resulted in Plaintiff's injuries and revision surgery.

b. The ATTUNE Knee system that Plaintiff received was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff's health care providers, including Dr. Xenos, of the full nature or extent of the risks associated with its use. The ATTUNE Knee system was not accompanied by a warning which specifically and fully informed Plaintiff's health care providers, including Dr. Xenos, of the risks of mechanical failure, inflammation, swelling, bone loss, and de-bonding associated with the implant.

79. Defendant knew or should have known of the dangers associated with the use of the ATTUNE Knee system as well as the defective nature of the ATTUNE Knee system. Such knowledge is evidenced by facts including, but not limited to:

a. Current medical literature documenting a causal link between the ATTUNE knee system and inflammation, swelling, bone loss, and de-bonding.

b. Prior lawsuits against Defendants alleging that the ATTUNE Knee system (or other similar implants) caused patients to suffer mechanical failure, inflammation, swelling, bone loss, and de-bonding.

80. The ATTUNE Knee system was in the above-described defective and unreasonably dangerous condition at the time Defendants placed in the stream of commerce.

81. The ATTUNE Knee system were expected to reach, and did reach, prescribing physicians and consumers, including Plaintiff, without substantial change in the condition in which they were sold.

82. At all times relevant, Plaintiff was a person in need of an artificial knee implant and thus a person Defendants should reasonably have expected to receive the ATTUNE Knee system.

83. Plaintiff and her medical providers used the ATTUNE Knee system as directed, and for their intended purposes.

84. At all times relevant, the ATTUNE Knee system was defective, and Defendants knew that they were to be used by consumers without inspection for defects therein. Moreover, neither Plaintiff nor her health care providers knew or had reason to know at the time of the use of the subject products, of the existence of the aforementioned defects. Neither Plaintiff nor her physician could have discovered the defects in the ATTUNE Knee system through the exercise of reasonable care.

85. The ATTUNE Knee system were not materially altered or modified prior to their use in Plaintiff.

86. The acts of Defendants were a cause of the injuries, damages, and losses of the Plaintiff.

SECOND CLAIM FOR RELIEF
(Negligent Products Liability – All Defendants)

87. Plaintiff incorporates all other allegations of this complaint as if fully rewritten.

88. Plaintiff suffered injuries, damages and losses in amounts to be proven at trial.

89. Defendants designed, manufactured, promoted, distributed, marketed, and sold the ATTUNE Knee System that injured plaintiff.

90. At all times relevant, Plaintiff was a person in need of an artificial knee implant and thus a person Defendants should reasonably have expected to receive the ATTUNE Knee System and ATTUNE Knee System.

91. At all times relevant, Defendants negligently failed to exercise reasonable care to prevent the ATTUNE Knee System from creating an unreasonable risk of harm to persons, including Plaintiff, who were using the device in a manner and for a purpose for which it was

made. Such negligence included, but is not limited to the following: a. Designing, manufacturing, promoting, distributing, marketing, and selling the ATTUNE Knee System prosthetic knee implant despite knowledge the prosthetic knee implants pose a risk of mechanical failure, inflammation, swelling, bone loss, and de-bonding. b. Failing to ensure that the ATTUNE Knee System was accompanied by specific warnings and/or instructions sufficient to fully inform consumers, including Plaintiff, of the risks of mechanical failure, inflammation, swelling, bone loss, and de-bonding associated with the implant. d. Failing to ensure that the ATTUNE Knee System was accompanied by specific warnings and/or instructions sufficient to and fully inform physicians, health care providers and other consumers, of the risk that they might have an adverse reaction to the implant. e. Failing to conduct adequate testing to determine whether the ATTUNE Knee System, with its design and construction, would mechanically fail or de-bond in a significant number of recipients.

92. The acts of the Defendants were a cause of the injuries, damages, and losses of the Plaintiff.

THIRD CLAIM FOR RELIEF
(Breach of Implied Warranties – All Defendants)

93. Plaintiff incorporates all other allegations of this complaint as if fully rewritten.

94. Plaintiff suffered injuries, damages and losses in amounts to be proven at trial.

95. Prior to the time that the ATTUNE Knee System and ATTUNE Knee System were used by Plaintiff's surgeon and healthcare providers, Defendants impliedly warranted to Plaintiff that the ATTUNE Knee System was of merchantable quality and safe and fit for the use for which it was intended.

96. Plaintiff's surgeon and healthcare providers did not research, design or manufacture medical devices such as the ATTUNE Knee System. Plaintiff's surgeon and

healthcare providers reasonably relied on the skill, judgment, and implied warranties of Defendants in deciding to use the ATTUNE Knee System and ATTUNE Knee System on their patients, including Ms. Dibala.

97. The ATTUNE Knee System was neither safe for its intended use nor of merchantable quality, as warranted by Defendants, in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user. Specifically: a. The mechanical failure of the ATTUNE Knee System subjected Plaintiff and others to risks, including the risk that Plaintiff would develop inflammation, swelling, bone loss, and de-bonding as a result of the implant, causing the implant to prematurely fail, and requiring Plaintiff to undergo a complex risky, and painful surgery to remove and replace the defective implant. b. The ATTUNE Knee System that Plaintiff received was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff of the full nature or extent of the risks associated with its use. The ATTUNE Knee System was not accompanied by a warning which specifically and fully informed Plaintiff of the risks of mechanical failure, inflammation, swelling, bone loss, and de-bonding associated with the implant.

98. Defendants, by selling, delivering and/or distributing the defective ATTUNE Knee System to Plaintiff breached the implied warranty of merchantability and fitness and caused Plaintiff to suffer severe pain and emotional distress, incur medical expenses and incur a loss of earning capacity.

99. The acts of the Defendants were a cause of the injuries, damages, and losses of the Plaintiff.

FOURTH CLAIM FOR RELIEF
(Breach of Express Warranty – All Defendants)

100. Plaintiff incorporates all other allegations of this complaint as if fully rewritten.

101. Plaintiff suffered injuries, damages and losses in amounts to be proven at trial.

102. At all times relevant, Defendants expressly warranted to Plaintiff's physicians, surgeons and other healthcare providers, by and through statements made by Defendants or their authorized agents or sales representatives, orally and in publications, package inserts and other written materials intended for physicians, medical patients and the general public, that the ATTUNE Knee System was safe, effective, fit, and proper for its intended use.

103. Plaintiff's physicians, surgeons and healthcare providers are not involved in the research, design and manufacture of medical devices such as the ATTUNE Knee System Plaintiff's physicians, surgeons and healthcare providers reasonably relied entirely on the skill, judgment, representations and foregoing express warranties of Defendants in using the ATTUNE Knee System.

104. Said representations and warranties were false in that the ATTUNE Knee System was not safe, effective, fit, and proper for its intended use in that it had dangerous propensities when put to its intended use and would cause severe injuries to the user. Specifically: a.) The design of the ATTUNE Knee System subjected Plaintiff and others to risks, including the risk of mechanical failure, that Plaintiff would develop inflammation, swelling, bone loss, and de-bonding as a result of the implant, causing the implant to prematurely fail, and requiring Plaintiff to undergo a complex risky, and painful surgery to remove and replace the defective implant. b.) The ATTUNE Knee System that Plaintiff received was not accompanied by adequate instructions and/or warnings to fully inform Plaintiff of the full nature or extent of the risks associated with its use. The ATTUNE Knee System was not accompanied by a warning which specifically and fully informed Plaintiff of the risks of mechanical failure, inflammation, swelling, bone loss, and de-bonding.

105. The acts of the Defendants were a cause of the injuries, damages, and losses of the Plaintiff.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays that this Court enter judgment in favor of Plaintiff and against Defendants, jointly and severally, in an amount that will compensate Plaintiff for all injuries, damages, and losses. Plaintiff prays for interest, both statutory and moratory, from the date of injury before and after judgment. Plaintiff prays for an award of costs, expert witness fees, reasonable attorney fees, and all other appropriate relief. Plaintiff reserves the right to amend this Complaint to add a claim for punitive damages at the appropriate time. Any further legal and equitable relief that the Court deems just and proper.

JURY DEMAND

PLAINTIFF HEREBY DEMANDS A TRIAL BY JURY ON ALL ISSUES AND CLAIMS, INCLUDING ALL CLAIMS AND CROSS-CLAIMS

DATED this 28th day of May, 2019.

Respectfully submitted,

BAITY & LINDVIG, LLC

s/ Stephen J. Baity

By: _____

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