JUL 2 4 2014

PONTiS™
ORTHOPAEDICS

510(K) Summary

Owner's Name	Leonard Gordon
Submitter Address	2299 Post Street Suite 107 San Francisco, CA 94115
Phone Number	(415) 567-8935
Fax Number	(415) 567-8934
510(k) Owner	PONTiS Orthopaedics, LLC
Contact Person	Leonard Gordon President
Date Prepared	June 24, 2014
Trade Name	P0NTiS™ Ultra-High Molecular Weight Polyethylene Suture and PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture
Common name	1. Suture, nonabsorbable, synthetic, polyethylene 2. Suture, Anchor
Classification Name	Class II 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener Class II 21 CFR § 878.5000 Nonabsorbable poly(ethylene terephthalate) surgical suture
Section	§C.F.R. Section 878.4495
Product Code	**P0NTiS™ Ultra-High Molecular Weight Polyethylene Suture** • GAT (suture, nonabsorbable, synthetic, polyethylene) **PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture** • MBI (fastener, fixation, nondegradable, soft tissue) • GAT (suture, nonabsorbable, synthetic, polyethylene)
Predicate Device	PONTiS™ Sutures and Suture Anchors with Optional Crimps K101126
Device Description	**Brief Description of the Device, Sutures** The PONTiS™ 3mm anchor is made of 316L stainless steel and incorporates non-absorbable UHMWPe sutures, which are

	available in United States Pharmacopoeia (USP) sizes 4-0 to 2-0 in various lengths and cleared to market under K094028. UHMWPe sutures and 316L Stainless steel are used in a wide variety of medical devices including previously approved implants of this type. The UHMWPe Sutures will be secured by knot tying. The UHMWPe sutures are supplied sterile and armed with cutting needles. A single use driver and hand piece will hold the excess suture, which delivers the preloaded anchor into the bone. The suture strands are used to reapproximate and secure the soft tissue to bone. The anchor is the same as was cleared under K101126, PONTiS Sutures and Suture Anchor with Optional Crimps.
Reason for 510(k)	Modified Device (suture change only)
Indications for Use	The PONTiS™ Nonabsorbable Ultra-High Molecular Weight Polyethylene Braided Suture are indicated to secure soft tissue to soft tissue reattachment in the hand: • Collateral Ligaments around the PIP, DIP and MCP Joints • Flexor and Extensor Tendons The PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture are indicated to secure soft tissue to bone reattachment in the hand: • Collateral Ligaments around the PIP, DIP and MCP Joints • Flexor and Extensor Tendons
Technological Characteristics	The PONTiS 3mm Suture Anchor is the same anchor cleared under K101126. All biocompatibility testing performed, which was conducted under the predicate submissions K101126 remain applicable for this submission as is contains the same materials. The suture material has changed to Ultra High Molecular Weight Polyethylene Suture. UHMWPe sutures, which was cleared under K094028. This indicates that the components are safe for their intended use. The PONTiS 3mm Anchor with UHMWPe as well as the predicate is a single use, implantable device, sterilized by ethylene oxide.

Substantial Equivalence	The substantial equivalence of the PONTiS™ Nonabsorbable Ultra-High Molecular Weight Polyethylene Braided Suture and PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture is based on the equivalence in intended use, operational principals, and indications for use to the predicate PONTiS™ Sutures and Suture Anchors with Optional Crimp (K101126). The only difference is the suture type, which is being changed to Ultra High Molecular Weight Polyethylene Suture (UHMWPe) instead of stainless steel. The sutures will be secured by knots instead of an alternate crimp. The UHMWPe sutures were cleared to market under K094028. PONTiS™ UHMWPe Sutures and PONTiS™ 3mm Suture Anchors with UHMWPe suture are substantially equivalent to other sutures currently marketed in conjunction with suture anchors and present no substantial differences in design, intended use and function to previously approved products.
Nonclinical Tests Performed	A collection of tests was conducted to determine safety and performance on the proposed device. Additionally, the subject device labeling is consistent both with FDA's guidance as well as current medical practice. The PONTiS™ 3mm Suture Anchors with UHMWPe was compared in standardized foam bone model materials. The Anchor insertion torque, suture strength (knot pull), pull-out failure mechanism (pull-out or suture break strength) and pullout failure force were documented. In addition cyclic pull-out performance was characterized. In all performance tests the PONTiS™ UHMWPe Sutures and 3mm Suture Anchors with UHMWPe Suture secured by knots are equivalent to products currently marketed for the same indications as confirmed by a comparison to the literature documenting the comparative characteristics of suture anchors. The performance studies and biocompatibility reviews indicate that the PONTiS™ UHMWPe sutures are safe for their intended use.
Conclusions Drawn	The testing demonstrated that the products are equivalent and did not affect safety and efficacy of the device or raise any new questions of safety or efficacy.

	Based on the indications for use, technological characteristics and performance test results, the PONTiS™ UHMWPe Sutures and 3mm Suture Anchors with UHMWPe suture is substantially equivalent to the predicate PONTiS™ Sutures and Suture Anchors with Optional Crimp K101126 and present no substantial differences in design, intended use and function.

END OF 510(k) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 24, 2014

PONTiS Orthopaedics, LLC
Dr. Leonard Gordon
President
2299 Post Street, Suite 103
San Francisco, California 94115

Re: K141711
Trade/Device Name: PONTiS™ Nonabsorbable Ultra-High Molecular Weight Polyethylene Braided Sutures and PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: MBI, GAT
Dated: June 24, 2014
Received: June 25, 2014

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Lori A. Wiggins

for
Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number (if known): K141711

Manufacturer: PONTiS Orthopaedics, LLC

Device Name: PONTiS™ Nonabsorbable Ultra-High Molecular Weight Polyethylene Braided Sutures and PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture

Indications for Use:

The PONTiS™ Nonabsorbable Ultra-High Molecular Weight Polyethylene Braided Sutures are indicated to secure soft tissue to soft tissue reattachment in the hand:

- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

The PONTiS™ 3mm Nonabsorbable Suture Anchors with Ultra-High Molecular Weight Polyethylene Braided Suture are indicated to secure soft tissue to bone reattachment in the hand:

- Collateral Ligaments around the PIP, DIP and MCP Joints
- Flexor and Extensor Tendons

Prescription Use (21 CFR Part 801 Subpart D)	XX	AND/OR	Over the Counter Use (21 CFR Part 801 Subpart C) __

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth [redacted]rank -S

Division of Orthopedic Devices