MAY 2 8 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
Date Prepared	April 22, 2014
Trade Name	ferroFIBRE™ with Crimp
Common name	Stainless Steel Suture
Classification Name	Stainless Steel Suture
Section	§C.F.R. Section 878.4495
Product Code	GAQ
Predicate Device(s)	ferroFibre™ (K081060) PONTiS™ Sutures and Suture Anchor with Crimps (K101126)
Device Description	The ferroFibre™ with Crimp is a nonabsorbable sterile surgical suture with a crimp composed of stainless steel. The ferroFibre™ with Crimp is available in USP sizes 4-0 to size 3, attached to stainless steel needles of various types and sizes. The ferroFibre™ suture was previously cleared in the K081060. A stainless steel crimp is being added to provide an alternate to knot tying. The use of the crimp for size 3-0 and 4-0 was cleared under submission K101126.
Reason for 510(k)	Device Modification – To allow the use of a crimp for securing size 3-0 to #3 ferroFibre™ cleared under K081060 as an alternate to knot tying.
Indications for Use	ferroFibre™ Stainless Steel Suture with Crimp is intended for use in soft tissue approximation and for use in abdominal wound closure, hernia repair, sternal closure and certain orthopaedic procedures including cerclage and tendon repair.

Technological Characteristics	The ferroFIBRE stainless steel suture is the same suture as was cleared under K081060. This submission includes the same crimp tool for 2-0, 3-0 and 4-0 as was cleared in K101126. A larger crimp tool will be used with the ferroFibre™ stainless steel sutures from 0 to size 3. The indications for use are the same as K081060. As for the crimps, each suture size and number of suture strands, 4 or 8, will require will require a different crimp size. All biocompatibility testing performed, which was conducted under the predicate submissions K101126 and K081060 remain applicable for this submission as the materials are the same. This indicates that the components are safe for their intended use. The PONTiS ferroFibre with Crimps is a single use, sterile implantable device, sterilized by ethylene oxide. The predicate devices are single use, sterile implantable device, sterilized by gamma irradiation and by ethylene oxide.
Substantial Equivalence	The PONTiS ferroFibre with Crimps are substantially equivalent in design, manufacturing materials, intended use, principles of operation, and technical characteristics to the predicates ferroFibre and Pontis Suture and Suture Anchors with Crimps. The risk analysis performed, raised no new issues of safety or effectiveness. The use of the crimp was cleared under the Pontis submission K101126, for size 3-0 to and 4-0 ferroFibre™. This submission expands the use of a crimp with the ferroFibre™ suture for the indications cleared under K081060.
Nonclinical Tests Performed	The verification and validation testing of the Pontis ferroFibre with Crimps includes knot failure force, crimp failure force and cyclic loading.
Conclusions Drawn	Non-clinical tests conducted demonstrates that the proposed device is safe, effective, and performs as well as the predicate devices, therefore demonstrating substantial equivalence.

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

May 28, 2014

PONTiS Orthopaedics, LLC
Mr. Leonard Gordon
President
2299 Post Street
San Francisco, California 94115

Re: K140127
Trade/Device Name: ferroFIBRE Stainless Steel Suture with Crimp
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless Steel Suture
Regulatory Class: Class II
Product Code: GAQ
Dated: April 22, 2014
Received: April 28, 2014

Dear Mr. 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" (21CFR 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510 (K) Number (if Known): K140127

Manufacturer: PONTiS Orthopaedics, LLC

Device Name: ferroFIBRE™ Stainless Steel Suture with Crimp

ferroFIBRE™ Stainless Steel Suture are intended for use in soft tissue approximation and for use in abdominal wound closure, hernia repair, sternal closure and certain orthopaedic procedures including cerclage and tendon repair.

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 Exemption (ODE)

Peter L. Hudson -S