510(K) Summary

Subject 510(k) Number: K101126

Sponsor
Core Essence Orthopaedics, Inc
575A Virginia Drive
Fort Washington, PA 19034

FDA Establishment Registration Number
3004613836

Official Contact
Jeff Miller
Vice President Operations
Core Essence Orthopaedics, Inc.
575A Virginia Drive
Fort Washington, PA 19034
Phone - (215) 310-9534
Fax - (215) 660-5015

Proprietary Name
1. PONTiSTM Sutures and Suture Anchors with Optional Crimps

Common Name
1. Suture Anchor, Stainless Steel Suture

Regulatory Class & Device Product Codes, Suture Anchors

Class II 21 CFR § 888.3040 Smooth or threaded metallic bone fixation fastener
Class II 21 CFR § 878.4495 Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Product Codes (Panel 87, Orthopedic):

PONTiSTM Suture Anchor with optional crimp
• MBI (fastener, fixation, nondegradable, soft tissue)

Date Prepared: November 26, 2010
PONTiSTM Sutures with optional crimp
• GAQ

The substantial equivalence of the PONTiSTM families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the Core Essence PONTiSTM ferroFibre stainless steel suture (K081060), the Pioneer Surgical SDB Cerclage System (K992616), the Ortheon Medical Tenofix tendon repair devices (K023594).

The substantial equivalence of the PONTiSTM 3.0mm suture anchors are based on the equivalence in intended use, materials, operational principals, and indications to reNOVOTM and other suture anchors including the Core Essence Orthopaedics reNOVOTM (K071520) and the J&J DePuy Mitek Micro Anchor (K962511).

Brief Description of the Device, Sutures with Crimp Collars

This premarket notification covers line extensions for the PONTiSTM product line. The ferroFibreTM stainless steel (SS) sutures were cleared for marketing in 2008, and are marketed in the PONTiSTM product group. The PONTiSTM product family has been expanded to include stainless steel suture anchors geometrically similar to the reNOVOTM titanium product family (cleared in 2007), in combination with ferroFibreTM SS Sutures and optional suture crimps.

The PONTiSTM implants incorporate non-absorbable ferroFibreTM 316L Stainless Steel Surgical sutures and are available in United States Pharmacopoeia (USP) sizes 4-0 and 3-0 in various lengths.

316L Stainless steel is used in a wide variety of medical devices including previously approved implants of this type. The ferroFibreTM Stainless Steel Sutures may be secured by either knot tying or crimping with a collar.

The ferroFibreTM multifilament sutures are supplied sterile, armed with cutting needles.

The implant components also include stainless steel collars specific to each suture size. The collars are used to secure multiple suture strands together simultaneously by crimping. For example, crimps are sized to accept between four (4) and eight (8) strands of each specific size of ferroFibreTM suture for crimping. A crimping instrument is supplied to crimp the collars to the suture strands. An adjustable tendon holder with suture tensioning slots is provided to facilitate suture cable tightening and tensioning. Excess suture is cut and removed.
Indications for Use

PONTiSTM Sutures with Optional Crimps 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

Safety and Performance, PONTiTSTM Anchors with ferroFibreSTM Sutures and Crimp Collar Securing Method

A collection of tests was conducted to characterize biocompatibility, diameter and tensile strength of the sutures in accordance with:

- ISO 10993 standards
- USP 32-NF 26 Monographs <861>, <871>, <881>
- Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003

In addition, a crimped suture loop pull-strength test was developed and used to verify that multiple sutures secured together using a crimped multi-strand collar had sufficient strength to secure a tendon repair. In the performance tests, the PONTiTSTM Sutures secured with Crimp Collars had sufficient strength and exhibited equivalent results to knot-secured suture products currently marketed for hand tendon repair as confirmed by a comparison to knotted sutures and to the literature.

The Crimp-Collar-secured multi-strand suture tensile strengths were sufficient to support active motion without resistance following tendon reattachment in the hand.

All materials were subjected to biocompatibility reviews or tests including cytotoxicity, sensitization, and irritation. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices). The performance studies and biocompatibility reviews indicate that the PONTiTSTM Sutures, secured with crimped Collars are safe for their intended use.

Basis for Substantial Equivalence, Sutures with alternate Crimp Collar securing method:

Core Essence Orthopaedics PONTiTSTM ferroFibreSTM sutures secured with crimp collars are substantially equivalent to other sutures currently marketed in conjunction with suture anchors and present no substantial differences in design, material, intended use and function to previously approved products. Additionally, the subject device labeling is consistent both with FDA's guidance as well as current medical practice.

The substantial equivalence of the PONTiTSTM families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the Core Essence
PONTiS™ ferroFibre stainless steel suture (K081060), the Pioneer Surgical SDB Cerclage System (K992616), the Ortheon Medical Tenofix tendon repair devices (K023594).

**Brief Description of the Device, Suture Anchors**

**PONTiS™ Suture Anchors**

The stainless steel PONTiS™ Suture Anchors are 3.0mm in diameter, are self-tapping, and fully threaded. The anchors are each available with 4-0 and 3-0 multi-strand ferroFibre™ stainless steel sutures. A disposable anchor driver holds the excess suture and delivers the anchor directly into the bone. The strands are then used to secure the soft tissue to bone.

Prior to installation, a hole is created in the bone using k-wire, drill or punch. The anchor is threaded into this hole. The anchor has self-tapping flutes.

Unlike the previously cleared titanium reNOVO™ Suture Anchor, PONTiS™ Suture Anchors are fully threaded allowing thread fixation in both cancellous and cortical bone.

The shorter overall length of the 3.0mm anchors, when compared to the self-drilling titanium reNOVO™ anchors, allows use in smaller/thinner bones where a lower profile is needed to achieve results without subsequent tissue injury.

The PONTiS™ threaded suture anchors are stainless steel to assure compatibility with the stainless steel in the ferroFibre™ stainless steel multi-strand sutures and the stainless steel crimp collars.

The size of the nonabsorbable stainless steel ferroFibre™ sutures used in the PONTiS™ Anchors is USP 4-0 and 3-0.

A single use driver and hand piece holds the excess suture and delivers the preloaded anchor into the bone. The suture strands are used to reapproximate and secure the soft tissue to bone.

The PONTiS™ Suture Anchors are provided sterile for single use applications.

The sizes and materials are designed to address the indications cited.
Indications for Use

**PONTiSTM Suture Anchors with Optional Crimps** 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**

Safety and Performance, Suture Anchors

The following safety and performance data has been provided to support substantial equivalence of the **PONTiSTM Suture Anchors** to **reNOVO**™ suture anchors.

Performance Testing: The **reNOVO**™ and the **PONTiSTM Suture Anchors** were 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 pull-out failure force were documented. In addition cyclic pull-out performance was characterized. The insertion torque was quantified in hard bone (bovine cortical bone) to assure the integrity of the anchor and anchor driver interface. The suture anchors were also functionally (vs. empirically) evaluated in animal and human cadaver bone by surgeons and engineers. The pullout strengths were sufficient to support active motion without resistance following tendon reattachment in the hand.

In all performance tests the **PONTiSTM Sutures** and Anchors secured by knots or crimps exhibited equivalent results to products currently marketed for the same indications as confirmed by a comparison to the literature documenting the comparative characteristics of suture anchors.

All materials were subjected to biocompatibility reviews or tests including cytotoxicity, sensitization, and irritation. The performance studies and biocompatibility reviews indicate that the **PONTiSTM Sutures and Anchors** are safe for their intended use.

Basis for Substantial Equivalence

The substantial equivalence of the **PONTiSTM** 3.0mm suture anchors are based on the equivalence in intended use, materials, operational principals, and indications to **reNOVO**™ and other suture anchors including the Core Essence Orthopaedics reNOVO™ (K071520) and the J&J DePuy Mitek Micro Anchor (K962511).

Relative to the hand, the **PONTiSTM** suture anchors have the same intended use (bone anchoring function), but different technological characteristics than the Mitek Micro-Anchors. (threads vs. barbs). The barbed predicate device from J&J Mitek incorporates the USP 4-0 suture sizes like the **PONTiSTM** suture anchors, and is indicated for soft tissue reattachment procedures in the hand.

The 3.0mm **PONTiSTM** suture anchors have threaded profiles similar to the 3.0mm **reNOVO**™ anchors. The **PONTiSTM** suture anchors are minor modifications of the
original titanium reNOVO™ anchors, and are indicated for the same procedures in the hand. The PONTiST™ suture anchors will be sold pre-assembled with stainless steel ferroFibre™ suture.

Conclusion

The substantial equivalence of the PONTiST™ families of sutures and crimp collars is based on the equivalence in intended use, materials, operational principals, and indications to other metallic sutures or cables secured with a crimp, including the SBD Cerclage system and the Tenofix tendon repair system.

The Core Essence Orthopaedics PONTiST™ sutures used in the anchors are substantially equivalent to the previously cleared Core Essence ferroFibre™ sutures, and the Core Essence Orthopaedics PONTiST™ suture anchors are substantially equivalent to reNOVO™ and J&J Mitek Micro-Anchors currently marketed, and present no substantial differences in design, material, intended use and function.

END OF 510K SUMMARY
Core Essence Orthopaedics, Inc.
% Mr. Jeff Miller
Vice President Operations
575A Virginia Drive
Fort Washington, Pennsylvania 19034

Re: K101126
   Trade/Device Name: PONTiS™ Sutures and Suture Anchors with Optional Crimps
   Regulation Number: 21 CFR 888.3040
   Regulation Name: Smooth or threaded metallic bone fixation fastener
   Regulatory Class: II
   Product Code: MBI, GAQ
   Dated: November 26, 2010
   Received: November 29, 2010

Dear Mr. Miller:

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.

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 go to [http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm) for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. 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](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 Small Manufacturers, International and Consumer Assistance 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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

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

Enclosure
Statement of Indications for Use

510 (K) NUMBER IF KNOWN: K101126
MANUFACTURER: Core Essence Orthopaedics, Inc.
DEVICE NAME: PONTiSTM Sutures and Suture Anchors with Optional Crimps

PONTiSTM Sutures with Optional Crimps 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

PONTiSTM Suture Anchors with Optional Crimps 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 XX and/or Over-the-Counter Use NO
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(Please do not write below this line - continue on another page, if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)