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510(K) SUMMARY

Subject 510(k) Number _____

Sponsor

Core Essence Orthopaedics, LLC

301 Oxford Valley Road
Suite 905B
Yardley, PA 19067

DEC 24 2008

FDA Establishment Registration Number

3004613836

Official Contact

Shawn T. Huxel, CEO & President
Core Essence Orthopaedics, LLC
301 Oxford Valley Road
Suite 905B
Yardley, PA 19067
Phone - (215) 310-9534
Fax - (609) 482-4957
Mobile - (908) 896-5893

Proprietary Name

ferroFibre™ Stainless Steel Suture

Common Name

Stainless Steel Suture

Classification Name and Reference

§878.4495 Suture, Nonabsorbable, Steel, Monofilament and Multifilament, Sterile

Regulatory Class

Class II (Special Controls Guidance Document: Surgical Sutures; Guidance for Industry and FDA; Dated June 3, 2003)

Device Product Code

GAQ

Date Prepared

8 April, 2008

Brief Description of Device

The ferroFibre™ Stainless Steel Suture is available in United States Pharmacopoeia (USP) sizes 5-0 to #5 in various lengths. The ferroFibre multifilament stainless steel

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sutures are supplied sterile, armed with cutting needles. The sutures are fabricated from 316 stainless steel that meets ASTM F138-03.

Indications for Use

ferroFibre Stainless Steel Surgical Sutures are indicated 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.

Discussion of Performance Testing

A collection of tests has been conducted to characterize biocompatibility, diameter and tensile strength in accordance to:

- ◊ ISO 10993 standards
- ◊ USP 31- NF 26 Monographs <861>, <871>, <881>
- ◊ Class II Special Control Guidance, Surgical Suture; Guidance for Industry and FDA, June 3, 2003

Conclusion

Core Essence Orthopaedics ferroFIBRE Stainless Steel Sutures are substantially equivalent to currently marked devices 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.

END OF 510(K) SUMMARY

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Core Essence Orthopaedics, LLC
% Mr. Shawn T. Huxel
CEO and President
301 Oxford Valley Road, Suite 905B
Yardley, Pennsylvania 19067

DEC 24 2008

Re: K081060
Trade/Device Name: Core Essence Orthopaedics, LLC
Regulation Number: 21 CFR 878.4495
Regulation Name: Stainless steel suture
Regulatory Class: II
Product Code: GAQ
Dated: November 28, 2008
Received: December 1, 2008

Dear Mr. Huxel:

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 such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Statement of Indications for Use

510 (K) NUMBER IF KNOWN: K081060

MANUFACTURER: Core Essence Orthopaedics, LLC

DEVICE NAME: ferroFibre Stainless Steel Suture

ferroFibre™ Stainless Steel Sutures 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 XX
(Per 21 CFR 801.109)

or

Over-the-Counter Use NO
(Optional Format 1-2-1996)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081060