K102201

p. 1/2

510(k) SUMMARY

DEC 15 2010

Summary Date:	December 4, 2010
Submitter Data:	Orthofix Inc. 1720 Bray Central Drive McKinney, TX 75609 214-937-2000 214-937-2736 (fax)
Primary Contact:	Darla Chew darlachew@orthofix.com
Device Trade Name:	Contours Lapidus Plating System
Common Name:	bone plate
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories. (21 CFR Parts 888.3030
Product Code:	HRS
Legally Marketed Predicate Device:	Darco ® Locking Plate System: K061808 / August 17, 2006
Device Description:	The Contours Lapidus Plating System consists of bone plates, screws and manual, orthopedic, surgical instruments. The plates (left and right versions) are low-profile and anatomically contoured for the 1st metatarsal and cuneiform. Each plate has a trapezoidal screw hole geometry with three angled, threaded holes at both the distal and proximal ends as well as a compression hole for intraoperative compression across the joint. The Contours Lapidus plate and bone screws are made from titanium alloy conforming to ASTM F136.
Indications for Use:	The Contours Lapidus Plating System is intended for revision procedures and joint fusion in the small bones of the foot.
Biomechanical Testing:	In order to demonstrate that the Contours Lapidus Plating System has the mechanical properties necessary to perform its intended use and to perform as well as the predicate device, Orthofix has conducted mechanical and functional testing of the Contours Lapidus Plating System. This testing includes bending strength, bending stiffness, fatigue life, screw torque and cadaveric functional testing. The results of the testing demonstrated the Contours Lapidus Plating System to meet or exceed all testing requirements and to perform as well as the predicate device.

Technological Characteristics:

The Contours Lapidus Plating System is considered to be substantially equivalent in design, intended use and material to the predicate device. However, there are certain design differences, but these do not raise new questions regarding safety and effectiveness. Refer to the Table of Technological Characteristics for a summary.

Features	Contours Lapidus Plating System
Indications for Use	The Contours Lapidus Plating System is indicated for revision procedures and joint fusion in the small bones of the foot.
Plate/Screw Material	Implant grade Titanium (Ti6A14V ELI)
Plate Size	50mm x 16mm x 2mm (left and right versions)
Plate Geometry	Low-profile, anatomically shaped for 1st metatarsal and cuneiform bones.
Fixation Method, Screw Holes	Trapezoidal screw hole placement. Three in proximal end, three in distal end plus compression hole.
Screw Type	Low profile, locking, non-locking and compression
Screw Length	Locking and non-locking screws: 12mm to 32mm lengths (in 2mm increments); compression screws are offered in sizes ranging from 16mm to 20mm lengths (in 2mm increments), 25mm to 40mm lengths in 5mm increments, and 42mm to 50mm lengths (in 2 mm increments)

Sterilization:

The Contours Lapidus Plating System components are supplied NON-STERILE and require sterilization prior to use.

Substantial Equivalence:

Substantial equivalence is based upon design, dimension, material characterization, and biomechanical testing of the device in comparison to the predicate. The Contours Lapidus Plating System is substantially equivalent in design and function to the Darco Locking Plate System which was cleared under K061808 / August 17, 2006.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

DEC 15 2010

Orthofix, Inc.
% Ms. Mary E. Biggers, RAC
Regulatory Affairs Consultant
1720 Bray Central Drive
McKinney, Texas 75069

Re: K102201
Trade/Device Name: Contours Lapidus Plating System (bone plate)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS
Dated: December 4, 2010
Received: December 8, 2010

Dear Ms. Biggers:

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 go to 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 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.

Sincerely yours,

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

Enclosure

K102201

p. 1/1

INDICATION FOR USE STATEMENT

Page ____ of _____

510(k) Number (if known): _____

Device Name: **Contours Lapidus Plating System (bone plate)**

Indications for Use:

The Contours Lapidus Plating System is intended for revision procedures and joint fusion in the small bones of the foot.

Prescription Use: X (Per 21 CFR 801.109) Or Over-The-Counter___ (Optional Format 1-2-96)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K102201