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SUMMARY OF SAFETY AND EFFECTIVENESS

OCT 2 0 2010

Orthofix Inc.
Contours VPS III Volar Plating System

Summary Date:	September 12, 2010
510(k) Submitter:	Mary E. Biggers, RAC / Orthofix Inc. 1720 Bray Central Drive McKinney, TX 75609 972-824-4624
Primary Contact:	Darla Chew / Directory, Regulatory Affairs/Orthofix Inc. Phone: 469-742-8824 Fax: 469-742-2556 darlachew@orthofix.com
Device Trade Name:	Contours VPS III Volar Plating System
Common Name:	bone plate
Regulation Name:	Single/multiple component metallic bone fixation appliances/ accessories.
Classification Name:	Plate, fixation, bone (21 CFR Parts 888.3030)
Product Code:	HRS
Indications for Use:	The Orthofix Contours VPS III is intended for volar fixation of fractures and osteotomies involving the distal radius.
Predicate Device:	The Orthofix Inc. Contours VPS III is substantially equivalent in design, function, and intended use to the Orthofix Volar Distal Radial Plate. The Volar Distal Radial Plate, manufactured by Orthofix Inc. of McKinney, TX, was originally cleared by FDA under K042766 on November 16, 2004.
Device Description:	The Contours VPS is an anatomically contoured, delta-shaped plate intended for volar applications to the distal radius. The Contours VPS features an angled head with two rows of holes for placement of screws distally on the radius to secure bone fragments and provide stabilization. If a bone graft is required, access to the site is made possible by the opening in the plate that spans from the plate head to the distal portion of the shaft that may also be utilized for screw placement. The shaft of the Plate is placed proximally on the distal radius and offers a variety of K-wire and screw placement options for secure fixation to the external surface of the bone. The device provides the stabilization and fixation necessary in the treatment of distal radius fractures and osteotomies.

Biomechanical Testing

The mechanical properties of the modified Contours VPS III plates were tested in uni-axial compression to determine if the modified plates meet the same criteria for mechanical strength and stiffness as the predicate device. The results of the testing demonstrated that the Contours VPS exceeded all mechanical testing criteria.

Material:

The Contours VPS III plates and screws are made from titanium alloy, Ti6AL-4V ELI conforming to ASTM F136.

Sterilization:

The Contours VPS III is supplied NON-STERILE and requires sterilization prior to use.

Substantial Equivalence:

The Contours VPS III is substantially equivalent in design and function to the Orthofix Inc. Volar Distal Radial Plate which received 510(k) clearance under K042766 on 11-16-04.

Features	Orthofix Volar Distal Radial Plate®	Contours VPS
Indications for Use	Intended for the volar fixation of fractures and osteotomies involving the distal radius.	Identical
Material	Implant grade Titanium (Ti6A14V ELI)	Identical
Fixation Method	Bone Screws	Identical
Overall Design	One-piece, low-profile, concave plate with multiple screw attachment options in head and shaft.	Identical
Plate Features: **- Graft/Screw Hole**	Center hole (separate)	Merged center hole with oval hole for use as graft window or screw hole
- Screw Holes	Linear arrangement of screw holes	Non-linear arrangement of screw holes; addition of two metaphyseal screw holes
- Plate Thickness	2.3mm-2.4mm	3.4mm center plate thickness for added strength
Plate Sizes	Left and right versions, Three widths: 0.7 – 1.2 in. range Five lengths: 2.0-4.0 in. range (all 5 lengths available in each width)	Left and right versions; Three widths: 0.9 – 1.2 in. range (narrow, standard, wide) Three lengths: 2.0-4.3 in. range (Narrow/wide plates offered in short and long lengths; standard width offered in short, long, & extra long)
Plate Geometry	Delta-shaped	Delta-shaped

Conclusion: Based upon the results of biomechanical testing, the modified Contours VPS III plates and expanded range of sizes is substantially equivalent to the Orthofix Volar Distal Radial Plate. The Contours VPS III has the mechanical properties needed to perform its indications for use and is considered to be substantially equivalent to the predicate device in design, intended use, material and function.

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

Orthofix, Inc.
% Ms. Mary E. Biggers, RAC
1720 Bray Central Drive
McKinney, Texas 75609

OCT 20 2010

Re: K101936
Trade/Device Name: Contours VPS III Volar Plating System (bone plate)
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and appliances
Regulatory Class: II
Product Code: HRS, HWC
Dated: September 12, 2010
Received: September 24, 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

OCT 2 0 2010

INDICATION FOR USE STATEMENT

510(k) Number (if known): K101936

Device Name: **Contours VPS III Volar Plating System (bone plate)**

Indications for Use:

The Contours VPS III Volar Plating System is intended for the volar fixation of fractures and osteotomies involving the distal radius.

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)

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

510(k) Number K101936