SEP - 6 2005

510(k) Summary of Safety and Effectiveness

Orthofix MIOT Plating System

510(k) number K051945

1. General Information:

Proprietary Name	Orthofix MIOT Plating System
Common Name	Bone Plate
Regulatory Class	II
Device Classification	87HRS (21 CFR 888.3030)
Submitter	R. Sheridan Consulting, LLC 632 Dundee Drive Wilmington N.C. 28405 USA
Registration number	9680825
Contact Person	Rolando Stanghellini Via delle Nazioni 9 37012 Bussolengo (VR) Italy
Summary Preparation Date	July 2005

2. Description

The Orthofix MIOT plating system consists of bone plates made of stainless steel designed for the internal fixation of small bone fragments. They are anatomically precontoured and allow a customized fragment adapted approach. If necessary, they can be bent to acquire the desired angle. Plates are available in different shapes (straight, "L"–, "T"- and oblique– shape), in a left and a right configuration and come in different sizes. They are attached to the bone using stainless steel FFS wires. Plates can accommodate three, four or five FFS wires, depending upon its shape and size. Instrumentation is available for the insertion and removal of the plates.

3. Intended Use

The Orthofix MIOT Plating System is intended for non-load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures and reconstruction.

4. Substantial equivalence

Documentation is provided which demonstrated the Orthofix MIOT Plating System to be substantially equivalent to other legally marketed devices.

Both the Orthofix MIOT Plating System and the predicate Smith & Nephew TC-100 mini-plate system are bone fixation systems as defined in 21 CFR 888.3030. These implantable devices consist of a small shaped bone plates held in place to stabilize and fix small bone fragments. The size, shape, and materials for the Orthofix MIOT Plating System are comparable to the predicate

5. Conclusion

Based upon the similarities in design, materials and intended uses of the Orthofix MIOT Plating System is substantially equivalent to the predicate devices.

K051945-P2/2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2005

Orthofix SRL
c/o Ms. Candace F. Cederman
R. Sheridan Consulting, LLC
632 Dundee Drive
Wilmington, North Carolina 28405

Re: K051945
Trade/Device Name: Orthofix MIOT Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: July 12, 2005
Received: July 18, 2005

Dear Ms. Cederman:

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.

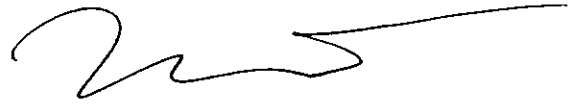
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K051945

Device Name: Orthofix MIOT Plating System

Indications for Use: The Orthofix MIOT Plating System is intended for non-load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures and reconstruction.

Prescription Use: X Or Over-The-Counter_____
(Part 21 CFR 801 Subpart D) (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)

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

510(k) Number K051945