# 510(k) Summary of Safety and Effectiveness

## Orthofix Titanium Humeral Plating System "LSP"

510(k) K062920

NOV 13 2006

## 1. General Information:

| | |
|---|---|
| **Proprietary Name** | Orthofix Titanium Humeral Plating System "LSP" |
| **Common Name** | Bone plate |
| **Regulatory Class** | II |
| **Device Classification** | 87 KTW (21 CFR 888.3030) |
| **Registration number** | 9680825 |
| **Contact Person** | Rolando Stanghellini<br>Via delle Nazioni 9<br>37012 Bussolengo (VR)<br>Italy |
| **Summary Preparation Date** | September 22nd, 2006 |

## 2. Description

The Orthofix Titanium Humeral Plating System consists of bone plates and locking screws, made of a titanium alloy. The bone plate included in the system is designed to treat fractures of the proximal humerus and come in a right and left version.

The plate has several locking options for the insertion of Fragment Fixations System implants (FFS), thus allowing a customized fragment adapted approach. Accessories include a cover to protect the ends of the FFS and a screw to lock this cover on the plate.

Instrumentation is available for the insertion of the plates and screws.

## 3. Intended Use

The Orthofix Titanium Humeral Plating System is intended for fractures, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

## 4. Substantial equivalence

Documentation is provided which demonstrates the Orthofix Titanium Humeral Plating System to be substantially equivalent to another legally marketed device. The plates included in the Orthofix Titanium Humeral Plating System and the predicate device, are both metallic bone fixation systems as defined in 21 CFR 888.3030, furthermore, the size, shape and materials for the subject devices are comparable to the predicate devices.

## 5. Conclusion

Based upon the similarities in design, materials and intended uses of the subject and predicate device, it is concluded that the Orthofix Titanium Humeral Plating System is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Orthofix SRL
% Ms. Candace F. Cederman
15058 Armel Drive
Oregon City, Oregon 97045

NOV 13 2006

Re: K062920
Trade/Device Name: Orthofix Titanium Humeral Plating System "LSP"
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Regulatory Class: II
Product Code: KTW
Dated: September 27, 2006
Received: September 28, 2006

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Buchman for

Mark N. Melkerson
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): K062920

Device Name: Orthofix Titanium Humeral Plating System

Indications for Use:

The Orthofix Titanium Humeral Plating System is intended for fractures, osteotomies and non-unions of the proximal humerus, particularly in osteopenic bone.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K062920