

NOV 1 2006

## 510(k) SUMMARY

### ADMINISTRATIVE INFORMATION

Manufacturer Name: Orthopedic Sciences, Inc.  
3020 Old Ranch Parkway,  
Suite 325  
Seal Beach, CA 90740

Official Contact: James K. Brannon, M.D. President/CEO  
Telephone (562) 799-5550 FAX (562) 799-5533

### DEVICE NAME

Classification Name: Plate, fixation, bone

Trade/Proprietary Name: *Titanium-TSY™* Shoulder Plate Implant

Common Name: Bone plate

### PREDICATE DEVICE INFORMATION

The predicate device for this modification is the TSY™ Shoulder Plate Implant, a component of the TSY™ Shoulder Plate Bone Graft Stabilization System, cleared by FDA on June 24, 2004 under K040850.

### INTENDED USE

The *Titanium-TSY™* Shoulder Plate Implant is intended to stabilize a bone graft within the humeral head and neck to assist healing of an intraosseous fracture.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Orthopedic Sciences, Inc.  
% James K. Brannon, M.D.  
President/CEO  
3020 Old Ranch Parkway, Suite 325  
Seal Beach, California 90740

NOV 1 2006

Re: K063033

Trade/Device Name: *Titanium-TSY™* Shoulder Plate Implant  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Smooth or threaded metallic bone fixation fastener  
Regulatory Class: Class II  
Product Code: HRS  
Dated: September 25, 2006  
Received: October 3, 2006

Dear Dr. Brannon:

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.

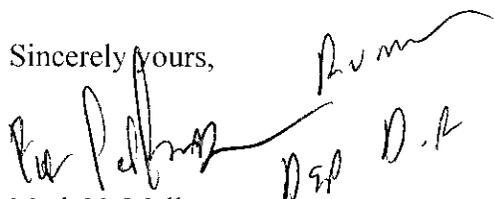
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – James K. Brannon, M.D.

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,



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): K063033

Device Name: Titanium-TSY™ Shoulder Plate Implant:

Indications For Use:

The Titanium-TSY™ Shoulder Plate Implant is intended to stabilize a bone graft within the humeral head and neck to assist healing of an intraosseous fracture.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

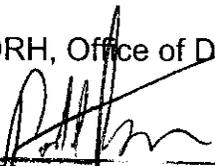
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number 12063033

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