K094037

510(k) Summary for the TC Plating System

MAR 1 0 2010

In accordance with 21 CFR 807.92 of the Federal Code of Regulations the following 510(k) summary is submitted for the TC Plating System

Date Prepared: 24 December 2009

1. **Submitter:**
OrthoPro LLC
3450 Highland Drive, Ste 303
Salt Lake City, UT 84106
801-746-1056

Contact Person:
J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** TC Plating System
Common Name: bone plate
Classification Name: Single/multiple component metallic bone fixation appliances and accessories
21 CFR § 888.3030
KTT
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
The TC Plating System is equivalent to previously cleared bone plating devices.

4. **Description of the device:**
The TC Plating System is comprised of a variety of titanium plates with shapes and sizes designed for internal fixation of small bone fragments. The plates include straight, right, and left configurations. The system also includes bone screws. Manual surgical instruments are supplied with the system to facilitate implantation.

Materials:
Titanium alloy (Ti 6Al 4V ELI) per ASTM F136

5. **Intended Use:**
The TC Plating System is intended for essentially non load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomaxillofacial skeleton.

6. **Comparison of the technological characteristics of the device to predicate and legally marketed devices:**
The TC Plating System is equivalent to the predicate devices in terms of:
   - Have the same indications for use and intended use
   - Have the same basic shape/design
   - Use the same operating principle
   - Utilize the same materials

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

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Ortho-Pro LLC
% The Orthomedix Group, Inc.
Mr. J.D. Webb
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K094037
Trade/Device Name: TC Plating System
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: February 26, 2010
Received: March 3, 2010

Dear Mr. J.D. Webb:

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

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,

for

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

Enclosure

Indications for Use

510(k) Number (if known): K094037

Device Name: TC Plating System

Indications for Use:

The TC Plating System is intended for essentially non load-bearing stabilization and fixation of small bone fragments in fresh fractures, revision procedures, joint fusion, and reconstruction of small bones of the hand, foot, wrist, ankle, humerus, scapula, finger, toe, pelvis, and craniomaxillofacial skeleton.

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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K094037