OCT 2 2 2003

510(k) Summary

K032282
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Date
August 26, 2003

Submitter
Ortho-Pro LLC
Box 515 4848 Highland Dr.
Salt Lake City, UT 84117

Contact person
J.D. Webb
1001 Oakwood Blvd
Round Rock, TX 78681
512-388-0199

Common name
Bone screw

Classification name
Screw, fixation, bone (per 21 CFR section 888.3040)

Equivalent Device
The STS Screw is similar in design, indications and material as the Kinetikos Subtalar MBA System (K960692).

Device Description
The Ortho-Pro STS Screw consists of a threaded implant, designed to be inserted between the posterior and middle facets of the subtalar joint and corresponding instrumentation to facilitate insertion. The implant is cylindrical in shape and incorporates a center cannula designed for use with a guide wire to facilitate proper placement of the implant. An internal hex-head allows for maximum torque with minimal risk of stripping. External rounded threads increase ease of insertion. This device is manufactured from Ti-6Al-4V alloy and is available in six sizes, Ø6.5mm to Ø11.5mm in 1mm increments.

Intended Use
The Ortho-Pro STS Screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela.
- Severely pronated foot
- Walking intemperance
- Calcaneal stance position greater than 5°
- Manually correctable deformities
- Mid-tarsal breech (arch pain)
- Forefoot varus greater than 10°

Summary of Technological Characteristics Compared to Predicate Device
- A minimally invasive, outpatient procedure
- Simplicity and accuracy
- Completely reversible procedure with minimal dissection required
- Entirely extra-articular, therefore, no bone resection or drilling is required, reducing trauma to bone and surrounding tissue
- No bone cement required
- Cannulated and constructed of highly biocompatible titanium
- Radiopaque
- Fully removable at skeletal maturity (in pediatric cases)
- Strong wear characteristics (titanium alloy will not fragment or wear like silicone or polyethylene devices)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 2 2003

Ortho-Pro LLC
C/o Mr. J. D. Webb
1001 Oakwood Boulevard
Round Rock, TX 78681

Re: K032682
Trade/Device Name: Ortho-Pro STS Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 26, 2003
Received: September 4, 2003

Dear Mr. 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.

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 (301) 594-4659. 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

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) number (if known): K032682

Device Name: Ortho-Pro STS Screw

Indications for Use:

Ortho-Pro STS Screw
Indications for Use

The Ortho-Pro STS Screw is indicated for use in treatment of the hyperpronated foot and stabilization of the subtalar joint. It is designed to block the posterior and inferior displacement of the talus, thus allowing normal subtalar joint motion while blocking excessive pronation and the resulting sequela. It is appropriate for the following conditions:

- Severely pronated foot
- Walking intemperance
- Calcaneal stance position greater than 5°
- Manually correctable deformities
- Mid-tarsal breech (arch pain)
- Forefoot varus greater than 10°

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ____ OR Over-the-Counter Use ____
(per 21 CFR 801.109)

(Optional format 1-2-96) ____

for Mark N Milhous

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

510(k) Number K032682