Ortho-Pro Cannulated Bone Screw
510(k) Summary
August 21, 2004

SEP 16 2004

K 042310

Submitter Ortho-Pro LLC
Suite 303
3450 Highland Dr.
Salt Lake City, UT 84106

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

Trade Name Cannulated Bone Screws

Common name Bone screw

Classification name Class II per 21 CFR section 888.3040

Product Code HWC

Equivalent Device Vilex Cannulated Screws (K991151).

Device Description
The Ortho-Pro Cannulated Bone Screw consists of a threaded implant and corresponding instrumentation to facilitate insertion. The implants are cylindrical in shape and incorporate 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. These screws are of the self-tapping type. This device is manufactured from Ti-6Al-4V alloy and is available in a variety of sizes.

Intended Use
The Ortho-Pro Cannulated Bone Screws are indicated for bone fractures, osteotomies, artrhodeses, osteochronditis and tendon reattachment.

These screws are not intended for attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

Summary of Technological Characteristics Compared to Predicate Device
The Ortho-Pro Cannulated Bone Screws are made from the same material, have the same indications and have similar thread form as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 2004

Ortho-Pro LLC
C/o Mr. J.D. Webb
OrthoMedix Group, Inc.
1001 Oakwood Boulevard
Round Rock, Texas 78681

Re: K042310
Trade/Device Name: Ortho-Pro Cannulated Bone Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: August 21, 2004
Received: August 25, 2004

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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): _____

Device Name: Ortho-Pro Cannulated Bone Screws

Indications for Use:

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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)

Miriam C. Provost

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

510(k) Number K042310