K091493

FEB - 5 2010

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date: January 25, 2010

Submitter:

Name:	ORTHO SELECT GmbH
Address:	Eltrastrasse 2 78573 Wurmlingen Germany
Contact Person:	Thomas Maier
Telephone:	+49.7461.9663230
Fax:	+49.7461.9663235

Product:

Trade Name:	ORTHO SELECT BONE PLATES AND SCREW SYSTEM
Classification:	HRS, HWC (Class II)
Common and Classification Names:	Bone Fixation Plate and Screw

Predicate Device:

- Smith & Nephew Bone Plate System (K993106)
- Synthes Bone Plates and Screws for Standard Osteosynthesis (Preamendment)
- Synthes Modular Foot System (K001941)

Device Description: The ORTHO SELECT Bone Plates and Screw System consists of stainless steel bone plate and bone screw implants intended for internal fixation of pelvic, small and long bone fractures according to the standard of the AO Foundation (AO Principles of Fracture Management). The bone plates and screws are provided non-sterile for steam sterilization by user and single use only.

Intended Use: The ORTHO SELECT Bone Plates and Screw System is used for adult or pediatric patients as indicated for pelvic, small, and long bone fracture fixation. Indications for use include fractures of the tibia, fibula, femoral condyle, pelvis, acetabulum, metacarpals, metatarsals, humerus, ulna, middle hand and middle foot bones; treatment of the calcaneal; and hip arthrodesis.

In pediatric patients, the ORTHO SELECT Bone Plates and Screw System is intended for use on mature bone only. It is not intended for placement across the growth plate.

Conclusion: The basic features, design and intended uses of the ORTHO SELECT Bone Plates and Screw System are similar or identical to those of the predicate devices. The minor differences in design and dimensions have no effect on the performance, function or intended use of the device and do not raise any new issues of safety and effectiveness. In summary, the applicant considers the ORTHO SELECT Bone Plates and Screw System to be substantially equivalent to the predicate devices.

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

ORTHO SELECT GmbH
% Ms. Angelika Scherp
Amstel 320-1
Amsterdam NL 1017AP

FEB - 5 2010

Re: K091493
Trade/Device Name: ORTHO SELECT BONE PLATES
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: February 1, 2010
Received: February 4, 2010

Dear Ms. Scherp:

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 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

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,

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): K091493

Device Name: ORTHO SELECT BONE PLATES AND SCREW SYSTEM

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Prescription Use __X__ AND/OR **Over-The-Counter Use** _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K091493