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K031609
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Attachment VI
Summary of Safety and Effectiveness Information
510(k) Summary

Sponsor:
Swiss Orthopedic Solutions Inc.
26 Turnstone Way
Downingtown, PA 19335
Phone: (610) 524-8142

Contact: Bob Bennett

Common Name: Bone Plate and Bone Screw

Classification Name: Single/multiple component metallic bone fixation appliance and accessories

Device Classification: Class II, 21 CFR 888.3030 and 888.3040

Name of Device: Swiss Orthopedic Solutions Inc., Small Fragment Locking Plate Set

Predicate Device: Synthes (USA) Dynamic Locking Compression (DCL) System, also known as the Locking Compression Plate Set.

Description of Device: The Swiss Orthopedic Solutions Inc. Small Fragment Locking Set is a plate and screw system. The available plate selection consists of straight, reconstruction, tubular, and various "T" and "L" shapes. The screws with the system are 3.6mm locking screws. The plates in the system can also accept standard spherical 2.7mm, 3.5mm and 4.0mm bone screws and cannulated bone screws. The plate features a hole that is fully threaded, allowing the use of any screw in a variety of positions. The system is available in either stainless steel or titanium.

Indications: The Swiss Orthopedic Solutions Inc. Small Fragment Locking Plate Set is a plate and screw system, intended to treat fractures osteotomies and non-unions of various bones, including but not limited to, the radius, ulna, proximal and distal tibia, pelvis, clavicle, fibula, humerus and scapula particularly in osteopenic bone.

Substantial Equivalence: The Swiss Orthopedic Solutions Inc., Small Fragment Locking Plate Set is considered substantially equivalent to the Synthes (USA) Dynamic Compression Locking (DCL) System, also known as the Locking Compression Plate Set.

Safety and Effectiveness: The plates which are included in this set, are manufactured of from biocompatible materials commonly used in the orthopedic industry. The plates were shown to exhibit strength characteristics comparable to the predicate devices. No new indications have been introduced with these devices. Therefore, the Swiss Orthopedic Solutions Inc. Small Fragment Locking Plate set is considered to be a safe and effective means of fracture fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2003

Mr. Bob Bennett
Swiss Orthopedic Solutions, Inc.
26 Turnstone Way
Downingtown, PA 19335

Re: K031609
Trade/Device Name: Swiss Orthopedic Solutions Inc., Small Fragment Locking Plate Set
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, KTT
Dated: May 20, 2003
Received: May 27, 2003

Dear Mr Bennett:

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

510(k) Number (if known): K031609

Device Name: Swiss Orthopedic Solutions Inc., Small Fragment Locking Plate Set

Indications for Use:

The Swiss Orthopedic Solutions Inc., Small Fragment Locking Plate Set is a plate and screw system, intended to treat fractures osteotomies and non-unions of various bones, including but not limited to, the radius, ulna, proximal and distal tibia, pelvis, clavicle, fibula, humerus and scapula particularly in osteopenic bone.

(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)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031609