K013954

Summary of Safety and Effectiveness

FEB 2 8 2002

Device Name: Lorenz Self Drilling Screw

Classification Name: Screw, Fixation, Bone

Device Product Code: 87HWC (21 CFR 888.3040)

Intended Use:

Internal fixation devices to aid the surgeon in the stabilization and fixation of oral cranio-maxillofacial skeletal bone, small bones of the hand, feet, wrist, ankles, fingers and toes, for the fixation of fractures, osteotomies, revision procedures, joint fusion and reconstructive procedures.

Description:

The self drilling screws are 1.5 mm to 2.0 mm in diameter and the thread lengths may range up to 7mm. The head may be center drive or cross drive. The tip of the screw is designed so that a predrilled hole is not required, but may be used.

Sterility Information:

The Lorenz Self Drilling Screws will be marketed as non-sterile, single use devices. Steam Sterilization recommendations are included in the package insert and can be seen in Attachment I.

Substantial Equivalence:

Walter Lorenz considers the Lorenz Self Drilling Screws equivalent to Synthes 1.3MM Self Drilling Screw (K983485), Osteomed Corp. Auto-Drive Bone Screw (K974785), and KLS Martin L.P. Centre-Drive Drill Free Screw (K971297). **TAB 3** includes a substantial equivalence comparison table to competitive devices. **TAB 4** includes sales information and/or Premarket clearance (510K) for Synthes, Osteomed Corp. and KLS Martin L.P.

Possible risks:

1. Poor bone formation, Osteoporosis, Osteolysis, Osteomyelitis, inhibited revascularization, or infection can cause loosening of the device.
2. Nonunion or delayed union which may lead to breakage of the implant.
3. Migration, bending, fracture or loosening of the implant
4. Metal sensitivity, or allergic reaction to a foreign body.
5. Decrease in bone density due to stress shielding.

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6. Pain, discomfort, abnormal sensation, or palpability due to the presence of the device.
7. Increased fibrous tissue response around the fracture site and/or the implant.
8. Necrosis of bone.
9. Inadequate healing.

Apart from these adverse effects there are always possible complications of any surgical procedure such as, but not limited to, infection, nerve damage, and pain which may not be related to the implant.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 8 2002

Ms. Kim Reed
Regulatory Specialist
Walter Lorenz Surgical, Inc.
1520 Tradeport Drive
Jacksonville, Florida 32218

Re: K013954
Trade/Device Name: Lorenz Self Drilling Screw
Regulation Number: 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: November 29, 2001
Received: November 30, 2001

Dear Ms. Reed:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K013954

Device Name: Lorenz Self Drilling Screw

Indications For Use:

Internal fixation devices to aid the surgeon in the stabilization and fixation of oral cranio-maxillofacial skeletal bone, small bones of the hand, feet, wrist, ankles, fingers and toes, for the fixation of fractures, osteotomies, revision procedures, joint fusion and reconstructive procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

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

510(k) Number K013954