K062842

W.LORENZ SURGICAL
A Biomet Company

1520 Tradeport Drive
Jacksonville, FL 32218
904-741-4400 fax 904-741-4500

510(k) Summary

DEC - 4 2006

Device Name: Lorenz Twist Drills

Classification Name and Reference:
CFR 882.4300 Manual cranial drills, burrs, trephines, and their accessories
CFR 882.4310 Powered simple cranial drills, burrs, trephines, and their accessories
CFR 872.4120 Bone cutting instrument and accessories
CFR 878.4800 Manual surgical instrument for general use
CFR 878.4820 Surgical instrument motors and accessories
CFR 888.4540 Orthopedic manual surgical instrument

Device Classification: Class II, Class I

Device Description: Lorenz Twist drills are drill bits which can either be attached to a manual instrument handle or attached to a powered handpiece/drill motor and used to drill holes in bone.

Intended Use: The Lorenz Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

Materials: Stainless Steel

Possible Adverse Effects:
1. Metal sensitivity reactions or allergic reaction to the implant material.
2. Pain, discomfort, or abnormal sensation due to the presence of the device.
3. Surgical trauma; permanent or temporary nerve damage, permanent or temporary damage to heart, lungs, and other organs, body structures or tissues.
4. Skin irritation, infection, and pneumothorax.
5. Fracture, breakage, migration, or loosening of the implant.
6. Inadequate or incomplete remodeling of the deformity or return of deformity, prior to or after removal of implant.
7. Permanent injury or death.

Substantial Equivalence

W. Lorenz considers the Lorenz Twist drills equivalent to the existing Twist drills which are classified as class I devices. W. Lorenz twist drills are also equivalent to Linvatec PowerPro Pneumatic System K032607 and Stryker Oral Max System K954690.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

DEC - 4 2006

Re: K062842
Trade/Device Name: Lorenz Twist Drills
Regulation Number: 21 CFR 882.4310
Regulation Name: Powered simple cranial drills, burrs, trephines, and their accessories
Regulatory Class: II
Product Code: HBE
Dated: November 17, 2006
Received: November 22, 2006

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), please contact the Office of Compliance at (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K062842

Device Name: Lorenz Twist Drills

Indications For Use: The Lorenz Twist Drills are intended to be used for drilling holes in large and small bone during orthopedic, spinal, neurosurgical, medial sternotomy, and oral and maxillofacial procedures.

Prescription Use __xx_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Brenner

(Division Sign-Off) Page 1 of _____

Division of General, Restorative, and Neurological Devices

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