

AUG 01 2002

510 (k) Summary

510 (k) Number:
K952847

K021342

Device Name:
Normed Bi-Directional / Multi-Directional Jaw Distractor

Device Identification:
External Mandibular Fixator and/or Distractor

Regulatory Class:
II

Product Code:
Product Code: JEY

Introduction of Normed Bi-Directional / Multi-Directional Jaw Distractor
510 (k) number K952847, by an additional distributor, Osteomedics® Inc.

The Normed Bi-Directional / Multi-Directional Jaw Distractor is authorized by Food and Drug Administration under the 510 (k) number K952847 to be distributed in the United States of America by Ace Surgical Supply Company, Incorporated¹. Osteomedics® Inc. is intended to be an additional distributor of the same device through out United States of America. The device intended to be introduced by Osteomedics® Inc., is the same identical product described in the 510 (k) number K952847. The manufacturer, product design, product material, manufacturing process, device description, product intend use, labeling², quality assurance procedures, sterilization, substantial equivalency information and operational principal is identical to the information available in the 510 (k) number K952847

Official Contact Person:

Albert Enayati
President
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Paramus, NJ 07652
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¹ Ace Surgical Supply Company, Incorporated, 1034 Pearl Street, P.O. Box 1710
Brockton , Massachusetts 02408

² Labeling will include Osteomedics® Inc. information.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 01 2002

Mr. Albert Enayati
President
Osteomedics, Incorporated
809 Carter Lane
Paramus, New Jersey 07652

Re: K021342
Trade/Device Name: Normed Bi-Directional/Multi-Directional Distractor
Regulation Number: 872.4760
Regulation Name: Bone Plate
Regulatory Class: II
Product Code: JEY
Dated: July 23, 2002
Received: July 25, 2002

Dear Mr. Enayati:

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.

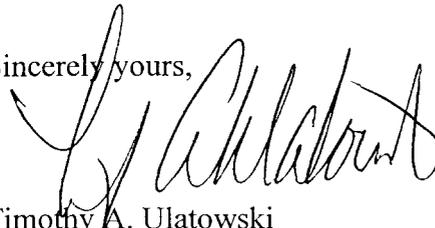
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You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 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) 594-4613. 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,



Timothy A. Ulatowski

Director

Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K021342

Indications for use

510 (k) Number (if known): K952847

Device Name: Normed Bi-Directional / Multi-Directional Jaw Distractor

Indications for use:

The intended use of the Normed Bi-Directional / Multi-Directional Jaw Distractor is identical to the description in the 510 (k) number K952847 in which, the Normed Bi-Directional / Multi-Directional Jaw Distractor is designed for use in bone elongation which takes into account and can reproduce the normal size and shape of the facial skeleton. As clinically defined the gradual step lengthening of a callus for distraction osteogenesis can be achieved with the transitory use of the Normed Bi-Directional / Multi-Directional Jaw Distractor. This Normed Bi -Directional / Multi-Directional Jaw Distractor device is indicated for use in maxillofacial alveolar and small craniofacial skeletal bones. Clinical indications are, sever open mandibular fractures, highly comminuted closed fractures, nonunion and delayed union, fractures associated with infection, tumor resections, facial deformity corrections, and bone – grafting defects.

Contraindications:

The Normed Bi-Directional / Multi-Directional Jaw Distractor is contraindicated in patients with insufficient available bone, poor bone quality and generalized diseases, allergies or habits (uncontrolled diabetes, blood dycrasias, hyperthyroidism, AIDS, alcohol addictions, psychiatric disorders, oral infections, malignancies, myocardial infection within the last 12 months, heavy smoking, use of chewing tobacco, poor oral-hygiene, etc.) that may contribute to poor healing or osteogenesis formation of bone. The patient's good medical health status and history is mandatory. In addition, a radiographic evaluation to examine the anatomical condition of the patient for proper use of the device to the defined surgical protocol is required.

(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)

(Optional Format 1-2-96)

Susan Resner

(Division Sign-Off)

Chief, Dental, Infection Control,
Federal Hospital Devices
Number K021342