



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**JUN 2 - 2005**

Mr. Andrew B. Rogers  
Director, Product Development and Special Projects  
Howmedica Leibinger, Incorporated  
14540 Beltwood Parkway East  
Dallas, Texas 75244

Re: K963030  
Trade/Device Name: Leibinger IMF Screw  
Regulation Number: 872.3640  
Regulation Name: Endosseous dental implant  
Regulatory Class: II  
Product Code: DZE  
Dated: March 12, 1997  
Received: March 13, 1997

Dear Mr. Rogers:

This letter corrects our substantially equivalent letter of March 12, 1997 regarding the incorrect product code of Leibinger IMF Screw.

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 (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 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.

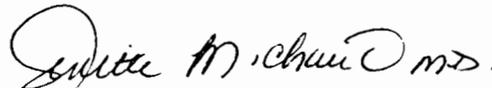
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 continue 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 (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

K963030

APR 11 1997

### 510(k) Summary

Device Proprietary Name: Leibinger® IMF Screw

Device Common Name: Small Bone Screw

Classification Name: Intraosseous Fixation Screw or Wire  
21 CFR 872.4880  
76 DZL

Name of Submitter: Howmedica Leibinger Inc.

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Date Prepared: March 12, 1997

#### Summary:

This submission describes a small bone screw intended for use in temporary maxillomandibular fixation to provide indirect stabilization of the maxilla, mandible, or both. The Leibinger® IMF Screw is 2.0 mm in diameter and ranges from 10.5-18.5 mm in total length (6-14 mm in threaded length). There is a hole in the screw head through which a wire can be passed to fix the maxilla and mandible. The device is for single use only.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Unisplint Dental Arch Bar (K820944); the Synthes Minihook and Cortical Screw (K# Unknown); the Synthes Cortical Bone Screw (K912932); and the Leibinger®-Luhr® Small Mandibular Bone Screws (K963740). The Dental Arch Bars, Minihook and Cortical Screw and Cortical Bone Screw are intended for use in maxillomandibular fixation to provide stabilization of fractures of the maxilla, mandible, or both. The Leibinger® IMF Screw and the Synthes Cortical Bone Screw can both be manufactured from commercially pure titanium; the Leibinger® IMF Screw and the Leibinger®-Luhr® Small Mandibular Bone Screws can both be manufactured from Ti(6Al,4V). The basic operational principle is similar for the cortical screw and arch bar devices.