

K970912

510(k) Summary

OCT - 1 1997

Device Proprietary Name: Leibinger® Self-Drilling Screw

Device Common Name: Small Bone Screw

Classification Name: Smooth or threaded metallic bone fixation fastener
21 CFR 888.3040

Name of Submitter: Howmedica Leibinger Inc.

Contact Person: Kristyn R. Waski
Quality Assurance/Regulatory Affairs Engineer
Howmedica Leibinger Inc.
14540 Beltwood Pkwy., East
Dallas, TX 75244
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Date Prepared: March 11, 1997

Date Revised: September 29, 1997

Summary:

This submission describes self drilling bone screws intended for use in internal fixation of small bones including the craniomaxillofacial skeleton and hand, secondary to trauma or for reconstruction. The Self Drilling Screw is available in 1.2 and 1.7 mm diameters with lengths ranging from 4-7 mm and in a 2.0 mm diameter with lengths ranging from 5-8 mm.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the KLS Martin Centre-Drive Drill-Free™ Screw [K944565] and the Leibinger® Luhr® Small Bone Screws [K963739, K963740 and K963741]. Each of the screw systems is intended for use in fixation of small bones secondary to trauma or for reconstruction. The Leibinger® Luhr® Small Bone Screws and the Leibinger® Self Drilling Screws are intended for use in craniomaxillofacial and hand fixation. The KLS Martin Centre-Drive Drill-Free™ Screws and the Leibinger® Self Drilling Screws are both designed as self drilling screws intended for use in internal fixation of the craniomaxillofacial skeleton. Each of the screw systems is manufactured from titanium alloy. The basic operational principle is similar for each of the named screw systems. The Leibinger® Self Drilling and KLS Martin Centre-Drive Drill-Free™ Screws are both self drilling and can be inserted in one step. Indications and contraindications are equivalent for each of the equivalent devices.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 1 1997

Ms. Kristyn R. Waski
Quality Assurance/Regulatory Affairs Engineer
Howmedica Inc.
Pfizer Hospital Products Group
14540 Beltwood Parkway East
Dallas, Texas 75244

Re: K970912
Trade Name: Leibinger® Self-Drilling Screw
Regulatory Class: II
Product Code: HWC
Dated: July 2, 1997
Received: July 3, 1997

Dear Ms. Waski:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

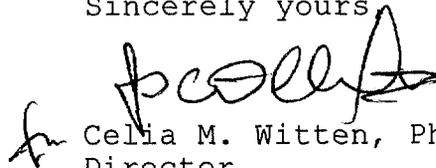
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 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 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): UNKNOWN AT THIS TIME

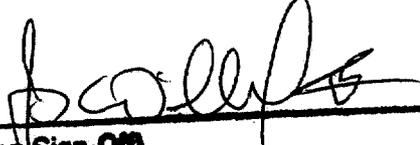
Device Name: Leibinger® Self Drilling Screw

Indications for Use:

This device is intended for use in internal fixation of small bones including the craniomaxillofacial skeleton and hand secondary to trauma or for reconstruction.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number _____

149709/2

Prescription Use X

OR

Over-The-Counter Use _____