

510(k) SUMMARY K 972154

Device Proprietary Name: Cohen Distractor All-
Device Common Name: Bone Distractor
Classification Name: Smooth or Threaded Metallic Bone Fixation
Fastener 21 CFR 888.3040
Name of Submitter: Howmedica Leibinger Inc.
Contact Person: John F. Dichiaro
Group Manger of Regulatory Affairs
Howmedica Leibinger Inc.
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Date Prepared: 6/5/97

Summary:

This submission describes a bone distraction system intended for use in the treatment of cranial, midfacial, or mandibular conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniosynostosis, midfacial retrusion, hemifacial microsomia, and mandibular micrognathia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial, midfacial, or mandibular bones. This device is a distraction system consisting of the following major components; distractor frame, plates, machine screws, flexible shaft, and distraction key. The plates and frame initially stabilize and then gradually distract the osteotomy. The flexible shaft, covered with a protective sheath, is connected to the frame and provides the point of attachment for the key used to initiate the distraction of the osteotomy.

Static cantilever bend testing was conducted on the Cohen Distractor and two currently available and legally marketed distraction devices, the Vazquez-Diner Distractor and the MULTI-GUIDE™ distractor (a.k.a. the Howmedica Mandibular Bone Distractor II). The results of the testing demonstrated that the Cohen Distractor had a significantly greater frame stiffness compared to the MULTI-GUIDE™ and Vazquez-Diner devices. The Cohen Distractor had an average yield strength which was significantly greater than the average yield strength of the MULTI-GUIDE™ device, and was slightly lower than the Vazquez-Diner device. It is not anticipated that this difference will have any relevance in the clinical setting because of the low forces observed in patients who are treated with all of these devices.

Equivalence for this device is based on similarities in intended use, material, design and operational principle to the Vazquez - Diner Intraoral Distractor (Howmedica Leibinger K964649); the Mandibular Bone Distractor II (Howmedica K960297); the Normed Distractor (Ace Surgical Supply [US Distributor] K # Unknown); the Luhr Small Fixation Plating System (Howmedica K950595) and the Synthes Midface Plating System (Synthes) K953806.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John F. Dichiara
Group Regulatory Affairs Manager
Howmedica, Inc.
Pfizer Hospital Products Group
359 Veterans Boulevard
Rutherford, New Jersey 07070-2584

AUG 11 1997

Re: K972154
K972166
Trade Names: Cohen Distractor
Guerrero-Bell Distractor
Regulatory Class: II
Product Code: JEY
Dated: June 6, 1997
Received: June 9, 1997

Dear Mr. Dichiara:

We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are 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 devices, 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.

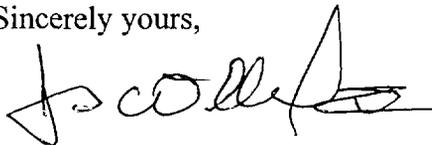
If your devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification

submissions 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.

This letter will allow you to begin marketing your devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4595. Additionally, for questions on the promotion and advertising of your devices, 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,


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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

Indications for Use

510(k) Number (if known) K972154
Device Name Leibinger Cohen Distractor

Indications for Use:

This product is intended for use in the treatment of cranial, midface, or mandibular conditions for which reconstructive osteotomy and segment advancement are indicated. This includes conditions such as, syndromic craniostenosis, midfacial retrusion, hemifacial microsomia, and mandibular micrognathia. The device is intended to provide temporary stabilization and gradual lengthening of the cranial, midfacial, or mandibular bones.

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

Concurrence of CDRII, Office of Device Evaluation (ODE)

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972154