

K973484

DEC - 2 1997

510(k) Summary

Device: Chin Distractor

The Chin Distractor is intended for use in patients requiring alveolar ridge augmentation of the mandible or maxilla. This includes conditions secondary to trauma, periodontal disease or birth abnormality. The device is intended to provide temporary stabilization and gradual expansion of the alveolar ridge. This device is a distraction osteogenesis system consisting of two bone plates, a threaded activation rod and a distraction instrument. The plates attach to bone using bone screws and then gradually distract the osteotomized segment via activation of the threaded rod with a distraction instrument. The implanted components of the device are manufactured from titanium.

The Chin Distractor is substantially equivalent to several other legally marketed devices. Examples of these are:

- | | | |
|----------------------------------------|---------------------|---------|
| 1. Cohen Distractor | Howmedica Leibinger | K972154 |
| 2. Luhr® Micro Mesh | Howmedica | K901940 |
| 3. Titanium Osteosynthesis System | W. Lorenz Surgical | K953385 |
| 4. Soft Tissue Expander (Versafil STE) | Cox-Uphuff Int. | K874276 |

For information contact:

John Dichiara
Group Regulatory Affairs Manager
Howmedica Inc.
359 Veterans Boulevard
Rutherford, NJ 07070
(201) 507-7386
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John Dichiaro
Group Regulatory Affairs Manager
Howmedica Incorporated
359 Veterans Boulevard
Rutherford, New Jersey 07070

DEC - 2 1997

Re: K973484
Trade Name: Chin Distractor
Regulatory Class: II
Product Code: JEY
Dated: September 12, 1997
Received: September 15, 1997

Dear Mr. Dichiaro:

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.

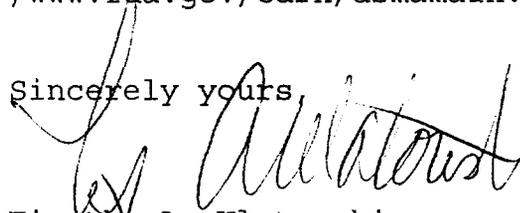
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

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) 594-4618. 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,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): Unknown

Device Name: Chin Distractor

Indications for Use:

This device is intended for use in patients requiring alveolar ridge augmentation of the mandible or maxilla secondary. This includes conditions secondary to trauma, periodontal disease or birth abnormality. The device is intended to provide temporary stabilization and gradual expansion of the alveolar ridge.

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

S. R. R. R. _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number 1673957

Prescription Use OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)