K963502

510(k) Summary

OCT 28 1997

Device Proprietary Name:	CSCO Forehead Fixation System
Device Common Name:	Bone Anchor
Classification Name:	Staple, Fixation, Bone Appliance for Reconstruction of Bone to Soft Tissue. 888.3030
Name of Submitter:	Howmedica Leibinger Inc.
Contact Person:	Kristyn R. Waski QA/RA Engineer Howmedica Leibinger Inc. 14540 Beltwood Pkwy., East Dallas, TX 75244 Telephone: (972) 392-3636 Fax: (972) 392-7258
Date Prepared: Date Revised:	August 30, 1996 July 28, 1997

Summary:

This submission describes a bone anchor device intended for use in endoscopic forehead or brow lift procedures. The CSCO Forehead Fixation System is a partially threaded bone screw 2.0 mm in diameter and available in either 12, 14 or 16 mm lengths. The distal 4 mm of each screw is threaded. The remainder of the shaft is smooth. The screw head is hexagonal and has a small groove just inferior to it for attachment of the suture. It is recommended that the CSCO Forehead Fixation System be removed after approximately 10-14 days to allow adherence of the newly elevated soft tissues to the underlying frontal bone. The device can be removed without anesthesia in the doctor's office.

Equivalence for this device is based upon similarities in intended use, material, design and operational principle to the Zimmer Statak Anchors (K926384), the Howmedica Mainstay Anchor (K953531), the Synthes Cortical Bone Screw (K912932), the Mitek® Threaded 2.0 mm Anchor (K961094), and the Marker System for Stereotaxic Navigation (K961120). The Statak, Mainstay and Mitek anchor devices are intended for use in reattachment of soft tissue to bone; the Cortical Bone Screw and Mitek anchor are used in endoscopic forehead lift procedures. The Statak, Mainstay and Mitek anchors are manufactured from Ti6Al4V, while the Cortical Bone Screw is manufactured from commercially pure titanium. The basic operational principle is similar for the anchor devices and the bone screw device. The Marker System for Stereotaxic Navigation relies on the principle of temporary percutaneous screw fixation for attachment to the skull.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

OCT 28 1997

Re: K963502
CSCO Forehand Fixation System
Regulatory Class: II
Product Code: MBI
Dated: July 28, 1997
Received: July 30, 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.

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): K963502

Device Name: CSCO Forehead Fixation System

Indications for Use:

The CSCO Forehead Fixation System is intended for use in an endoscopic forehead or brow lift procedure. This procedure is performed endoscopically through several small openings rather than through a trans-coronal incision, resulting in reduced scarring and blood loss for patients. The soft tissue is elevated off the underlying bone endoscopically and fixed in the higher position by tying sutures attached to the tissue of the scalp to the CSCO Forehead Fixation System anchored in the outer table of the skull. The CSCO Forehead Fixation System is attached to the skull through a small incision in the scalp. It is recommended that the CSCO Forehead Fixation System be removed after approximately 10-14 days to allow adherence of the newly elevated soft tissues to the underlying frontal bone.

(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 K963502

Prescription Use X OR Over-The-Counter Use _____

(Optional Format 1-2-96)