

JAN 30 1998

K974136

## 510(k) Summary of Safety and Effectiveness

**SUBMITTER:** Biomet, Inc.  
Airport Industrial Park  
P. O. Box 587  
Warsaw, IN 46581-0587

**CONTACT PERSON:** Mary L. Verstynen  
(219) 267-6639 ext. 1343

**PRODUCT CODE:** 79 GAN  
Device Name: Craniofacial Anchors

### SUMMARY

The Craniofacial Anchors are indicated for use with resorbable suture in open and endoscopic brow lift procedures. The device is placed into a predrilled, tapped bone hole and assists the suture in anchoring soft tissue. These devices are not designed for use in the mandible and/or full load bearing procedures.

The devices are made of LactoSorb® material, which based on animal studies, completely resorbs by 12 months *In Vivo*. The devices are made of bioresorbable and biocompatible polymers that have been used in surgical procedures for years. LactoSorb® resorbable copolymer is a synthetic polyester derived from lactic and glycolic acids. Polylactic/polyglycolic (PLA/PGA) acid copolymer degrades and resorbs *In Vivo* by hydrolysis to lactic and glycolic acids which are then metabolized by the body. The safety of PLA/PGA material has been well documented since the early 1970's when FDA first approved the use of resorbable PLA/PGA sutures. The exact same LactoSorb® material has been implanted in humans for over 10 years in the form of a ligating clip and safety and effectiveness has been studied in two different clinical trials. The LactoSorb® material has been found to be biocompatible in both soft and hard bone tissue and maintains its strength for soft tissue reattachment and fracture healing.

As demonstrated in this submission, the Craniofacial Anchors are safe and effective for use in brow lift procedures.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

30 1998

Ms. Mary Verstynen  
•Clinical Research Manager  
Biomet, Inc.  
Airport Industrial Park  
P.O. Box 587  
Warsaw, Indiana 46581-0587

Re: K974136  
Trade Name: Craniofacial Anchor  
Regulatory Class: II  
Product Codes: MBI, HWC, and GAN  
Dated: October 31, 1997  
Received: November 3, 1997

Dear Ms. Verstynen:

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.

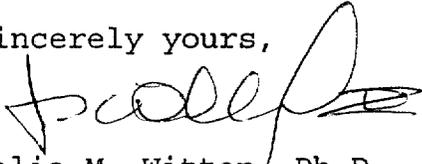
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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): K974136

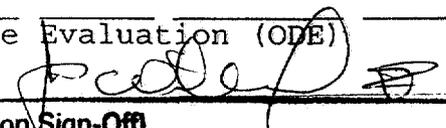
DEVICE NAME: Craniofacial Anchors

INDICATIONS FOR USE:

The Craniofacial Anchors are indicated for use to assist resorbable suture in open and endoscopic brow lift procedures.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974136

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use \_\_\_\_\_  
(Optional Format 1-2-96)