

MAR 27 1998

K972919

Attachment 16

510(K) SUMMARY FOR THE BIONX IMPLANTS, INC. BIOSORB®
BIODEGRADABLE THREADED ENDOBROW SCREW

Submitter's Name, Address, Telephone Number, And Contact Person

Bionx Implants, Inc.
1777 Sentry Parkway West
Gwynedd Hall Suite 400
Bluebell, PA 19422

Contact: David W. Anderson.
President and CEO
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Date Prepared

February 12, 1998

Name of the Device

BioSorb® Biodegradable Threaded Endobrow Screw

Common or Usual Name

Bioabsorbable Threaded Fixation Rod

Classification Name

Bone Fixation Screw

Predicate Devices

- (1) Techmedica, Inc. TMP Micoplate System (K921458)
- (2) W. Lorenz Surgical, Inc. LactoSorb® System (K955729)
- (3) Bionx Implants, Inc. BIOFIX® SR-PLLA Threaded Rod (K952871)
- (4) Synthes, Inc. PDLA Polypin (K961608)

Intended Use

The BioSorb® SR-PDLA Endobrow Screw is intended for use in endoscopic browplasty surgery. The Endobrow Screw will be specifically indicated for use to reattach the subdermis to the cranial bone in endoscopic browplasty procedures. The Endobrow Screw is used as a post to tie an absorbable suture to the subdermis. In conjunction with adequate surgical technique, the Endobrow Screw holds the subdermis securely in place to allow for reattachment to the cranial bone. Use absorbable sutures that provide wound support for at least thirty (30) days. The BioSorb® SR-PDLA Endobrow Screw will maintain sufficient physical integrity and mechanical holding properties within the bone well beyond the 30 days needed for complete biological healing and reattachment of the subdermis to the cranial bone.

Principles of Operation

After preparing the area according to standard surgical procedures, several small incisions are made just behind the frontal hairline based upon the elevation and direction needed for the patient. A subperiosteal plane is obtained and a drill hole is made in the cranial bone on one side of the head. The position of the drill hole is determined based upon the individual needs of each patient. The drill hole is made with an Aesculap power drill with a 1.5 mm x 3.7 mm bit and a 3.5 mm stop on the bit to prevent further penetration and injury to the dura. Once

endoscopic browplasty is completed, the accompanying screw-thread tap is used and the BioSorb® SR-PDLA Endobrow Screw is inserted 3.0 mm to 3.5 mm into the cranial bone. The BioSorb® SR-PDLA Endobrow Screw is used to tie an absorbable suture to the subdermis. An absorbable suture which provides wound support for at least thirty (30) days is recommended. The BioSorb® SR-PDLA Endobrow Screw provides secure fixation of the subdermis to the cranial bone to allow for reattachment of the soft tissue to the bone. The scalp is closed with a chromic suture and the procedure is repeated on the contralateral side.

Technical Characteristics

The BioSorb® SR-PDLA Endobrow Screw has the same intended use and principles of operation and very similar technical characteristics as the bone screws used in the previously cleared W. Lorenz LactoSorb System (K955729) and Techmedica TMP Microplate System (K921458) fixation systems. The BioSorb® SR-PDLA Endobrow Screw also is identical in technological characteristics to the previously cleared BIOFIX® Bioabsorbable Self-Reinforced Poly-L-lactide Threaded Fixation Rod for use in the ankle (K952871). Additionally, the BioSorb® SR-PDLA Endobrow Screw is constructed of the same blended copolymer used in the previously cleared Synthes Polypin (K961608).

Like the bone screws in the Lorenz and Techmedica products, the BioSorb® SR-PDLA Endobrow Screw is intended for use in endoscopic browplasty surgical procedures. All three types of screws are inserted into facial or cranial

bone to provide fixation; the Lorenz and Techmedica screws are inserted to hold a bone fixation plate in place, while the BioSorb® SR-PDLA Endobrow Screw is inserted as a post to hold fixation sutures that secure the subdermis so that reattachment to the cranial bone can occur during the healing process. All are 2.0 mm in diameter (the Lorenz and Techmedica products offer other sizes as well). Both the BioSorb® SR-PDLA Endobrow Screw and the Lorenz screw are bioabsorbable, although the former is made from PDLA and the latter from a PLA-PGA copolymer with a similar degradation period. Neither the BioSorb® SR-PDLA Endobrow Screw nor the Lorenz screws are self-tapping. The Techmedica screw is metallic and is self-tapping.

Finally, the BioSorb® SR-PDLA Endobrow Screw is identical in technological characteristics to the BIOFIX® Bioabsorbable Self-Reinforced Poly-L-lactide Threaded Fixation Rod for use in the ankle, although the two do not share the same anatomical site/ intended use. The BioSorb® SR-PDLA Endobrow Screw also is constructed of the same blended copolymer used in the previously cleared Synthes Polypin (K961608). Like the Endobrow Screw, the Polypin is an implantable orthopedic fixation device. The Polypin is intended for use in fixation of small bone fragments in “low load” fractures, while the Endobrow Screw is intended for the less demanding task of soft tissue approximation. The Polypin was found substantially equivalent to predicate devices composed of PLLA, polyglycolic acid (“PGA”), and polydioxanon. Thus, FDA has previously recognized that all of these polymers have similar physical properties and biocompatibility

characteristics. The BioSorb® SR-PDLA Threaded Endobrow Screw will degrade by hydrolysis over a period of 12 to 24 weeks *in vivo*, with complete reabsorption within two to four years after implantation.

Like its predicates, the BioSorb® SR-PDLA Endobrow Screw requires good surgical technique. The surgical instruments used for implantation of the BioSorb® SR-PDLA Endobrow Screw are the same as those cleared for use in implanting the currently marketed 2.0 mm BIOFIX® SR-PLLA Threaded Rod for use in the ankle.

Summary Basis for the Finding of Substantial Equivalence

Like the previously cleared TMP Microplate System, the Lactosorb®, and the BIOFIX® SR-PLLA Threaded Rod, the BioSorb® SR-PDLA Threaded Endobrow Screw is intended for use in endoscopic browplasty surgery. The BioSorb® SR-PDLA Endobrow Screw will be specifically indicated for use to reattach the subdermis to the cranial bone in endoscopic browplasty procedures. Although the indications for use of the screws differ slightly, all of the devices possess similar principles of operation and technical characteristics. The minor differences in the technical characteristics of the devices, such as differences in the configuration, do not raise new questions of safety or effectiveness. Thus, the devices are substantially equivalent.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 1998

Bionx Implants, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
Columbia Square
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K972919
Trade Name: Biosorb® Biodegradable Threaded
Endobrow Screw
Regulatory Class: II
Product Codes: HWC and MAI
Dated: January 5, 1998
Received: January 5, 1998

Dear Mr. Kahan:

We have reviewed your Section 510(k) notification of intent to market the device referenced above submitted on behalf of Bionx Implants, Inc. 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

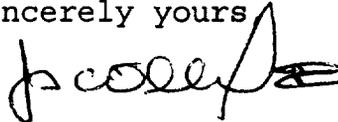
Page 2 - Mr. Jonathan S. Kahan

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



← 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): K972919

Device Name: BioSorb® Biodegradable Threaded Endobrow Screw

Indications For Use:

The BioSorb® SR-PDLA Endobrow Screw is intended for use in Endoscopic Browplasty surgery. The Endobrow Screw will be specifically indicated for use to reattach the subdermis to the cranial bone in endoscopic browplasty procedures. The Endobrow Screw is used as a post to tie an absorbable suture to the subdermis. In conjunction with adequate surgical technique, the Endobrow Screw holds the subdermis securely in place to allow for reattachment to the cranial bone. Use absorbable sutures that provide wound support for at least thirty (30) days.

(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

K972919

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)