K982139

SEP 15 1998

510(k) SUMMARY
BIONX IMPLANTS, INC.'S
BioSorbFX 1.5/2.0 Bioabsorbable Fixation System

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

Bionx Implants, Inc.
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Date Prepared

June 16, 1998

Name of the Device

BioSorbFX 1.5/2.0 Bioabsorbable Fixation System

Common or Usual Name

Bioabsorbable Craniofacial Bone Plates and Plate Fasteners

Classification Name

Bone Plate (Product Code 76JEY)

Predicate Devices

(1) Synthes, Inc. Resorbable Fixation System (K974554),
(2) Walter Lorenz Surgical, Inc. LactoSorb® Trauma Plating System (K974309, K971870, and K960988),
(3) Bionx BioSorb Endobrow Screw (K972919),
(4) Bionx Biodegradable Threaded Suture Anchor (K972783)

Intended Use

The BioSorbFX System is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating comminuted fractures of the naseothmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; trauma of the midface and craniofacial skeleton, and reconstructive procedures of the midface or craniofacial skeleton. The BioSorbFX System is used to stabilize bone during healing, in conjunction with appropriate postoperative immobilization. The BioSorbFX System includes an instrumentation set containing bone drills, bone taps, screwdrivers and plate benders.

The BioSorbFX System is not intended for use in and is contraindicated for: 1) the mandible; 2) full load bearing procedures; 3) areas with active infection; or 4) patient conditions, including blood supply limitations, insufficient quantity or quality of bone, or latent infections.

Device Description and Principles of Operation

The BioSorbFX System contains various plates, meshes and screws that are made from poly-L/D,L-lactide ("P(L/DL)LA") copolymer, which consists of 70 molar percent poly-L lactide and 30 molar percent poly-D,L-lactide. Plates and meshes are provided as either straight-edged or scalloped edged of varying thickness, lengths, and shapes (*e.g.*, rectangular, straight line, X-, L-, and C-shape). The plates are sized to be secured to the midface or craniofacial skeleton with a 1.5mm or 2.0mm bioabsorbable fastener (*i.e.*, threaded screw). The BioSorbFX System is supplied pyrogen free and sterile following gamma radiation sterilization and is not intended to be resterilized by the user.

The BioSorbFX System is used in standard surgical procedures for reconstructive surgery or in the treatment of fractures of the midface and craniofacial skeletons. In conjunction with adequate surgical technique, the appropriate sized bioabsorbable craniofacial plates are used to stabilize bone fragments by attachment of the plate to the bones with plate fasteners (*i.e.*, threaded screws). The BioSorbFX fasteners are inserted through the predrilled, counter sunk plate holes following drilling, pre-tapping, and flushing of the corresponding holes in the midface or craniofacial skeleton using standard surgical technique. The BioSorbFX fastener holds the BioSorbFX plate securely in place to allow for biological healing of the midface or craniofacial skeleton fracture or reconstruction. The plate remains securely fastened to the midface or craniofacial skeleton throughout the healing period, after which the plate and fasteners gradually degrade and are completely absorbed by the body. Thus, there is no need to surgically remove the devices.

Technological Characteristics and Substantial Equivalence

The BioSorbFX Bioabsorbable Fixation System ("BioSorbFX System") contains various plates and threaded fasteners made of a biodegradable poly-L/D,L-lactide ("P(L/DL)LA") copolymer, which consists of 70 molar percent poly-L lactide and 30

molar percent poly-D,L-lactide. The P(L/DL)LA material used in the BioSorbFX System is the same material used in other bioabsorbable devices previously cleared for implant use including the Bionx Implant Inc.'s Biodegradable Threaded Suture Anchor (K972783) and BioSorb Endobrow Screw (K972919), and Synthes, Inc. Resorbable Fixation System (K974555).

The BioSorbFX System has the same intended use and principles of operation and very similar technological characteristics as the bone plates and fasteners used in the previously cleared Synthes, Inc. Resorbable Fixation System (K974555) and the Walter Lorenz Surgical, Inc. LactoSorb® Trauma Plating System (K974309, K971870, and 960988). Like these predicate devices, the BioSorbFX System is intended for craniofacial trauma and reconstructive surgical procedures in the midface and craniofacial skeleton. All three fixation systems offer a variety of plate sizes and shapes and plate fasteners in both a 1.5 mm and 2.0 mm diameter size. Both the BioSorbFX System and the LactoSorb Trauma Plating System provide the user with customized instrumentation sets for use with their products. Additonally, the instrumentation set of the BioSorbFX System is similar to the instrumentation set included with Bionx's BioSorb Endobrow Screw (K972919).

The BioSorbFX System, the Synthes, Inc. Resorbable Fixation System and the LactoSorb Trauma Plating System are made of bioabsorbable materials. The BioSorbFX System and the Synthes, Inc. Resorbable Fixation System are made of the same biodegradable poly-L/D,L-lactide ("P(L/DL)LA") copolymer, while the LactoSorb is made of a reabsorbable copolymer consisting of a synthetic polyester derived from lactic and glycolic acids ("PLA/PGA"). All of these materials are biocompatible and have been shown to maintain sufficient physical integrity and mechanical holding properties within the bone for a sufficient period of time during the biological healing process. Unlike nonbioabsorbable fixation devices, the BioSorbFX System and the predicate devices do not require a second operation to remove the devices after the site has healed.

Summary Basis for the Finding of Substantial Equivalence

Like the previously cleared Synthes Resorbable Fixation System, and the Lorenz LactoSorb® Trauma Plating System, the BioSorbFX system has the same intended use and principles of operation and very similar technological characteristics. Furthermore, the BioSorbFX System is made of the identical biodegradable P(L/DL)LA material used in other Bionx products, including the Bionx Endobrow Screw and the Biodegradable Threaded Suture Anchor, and to the Synthes Fixation System, all of which have previously been cleared by the FDA for implant use. Any minor product design differences, such as differences in configurations, between the BioSorbFX System and the predicate devices do not raise any new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 15 1998

Bionx Implants, Incorporated
C/O Mr. Jonathan S. Kahan
Partner
Hogan & Hartson L.L.P.
Columbia Square
555 Thirteenth Street, N.W.
Washington, DC 20004-1109

Re: K982139
Trade Name: BioSorbFX 1.5/2.0 Bioabsorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: June 17, 1998
Received: June 17, 1998

Dear Mr. Kahan:

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 legally marketed predicate 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 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. 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) 594-4692. 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"(21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Patricia Cucuzza /for

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): _____

Device Name: BioSorbFX 1.5/2.0 Bioabsorbable Fixation System

Indications for Use:

The BioSorbFX System is intended for use in trauma and reconstructive procedures in the midface and craniofacial skeleton. Specifically, the device is indicated for use in treating comminuted fractures of the naseothmoidal and infraorbital areas; comminuted fractures of the frontal sinus wall; trauma of the midface and craniofacial skeleton, and reconstructive procedures of the midface or craniofacial skeleton. The BioSorbFX System is used to stabilize bone during healing in conjunction with appropriate postoperative immobilization. The BioSorbFX System includes an instrumentation set containing bone drills, bone taps, screwdrivers and plate benders.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-off)

Division of Dental, Infection Control, and General Hospital Devices

510(k) Number K982139

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)