2/17/99

K982721

K982721 "SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

REVIEWER: Pamela D. Scott DIVISION/BRANCH: DGRD/Dental

TRADE NAME: BioSorbFX 2.0/2.4 Orthognathic Bioabsorbable Fixation System

COMMON NAME: Bone Plates and Bone Screws

PRODUCT TO WHICH COMPARED: (510(k) NUMBER IF KNOWN) LactoSorb® Trauma Plating System (K971870) BioSorbFX 1.5/2.0 Bioabsorbable Fixation System (K982139)

	YES	NO	
1. IS PRODUCT A DEVICE?	x	☐	- IF NO STOP
2. DEVICE SUBJECT TO 510(k)?	x	☐	- IF NO STOP
3. SAME INDICATION STATEMENT?	x	☐	- IF YES GO TO 5
4. DO DIFFERENCES ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR EFFECTIVENESS?	☐	☐	- IF YES STOP - NE
5. SAME TECHNOLOGICAL CHARACTERISTICS?	x	☐	- IF YES GO TO 7
6. COULD THE NEW CHARACTERISTICS AFFECT SAFETY OR EFFECTIVENESS?	☐	☐	- IF YES GO TO 8
7. DESCRIPTIVE CHARACTERISTICS PRECISE ENOUGH?	x	☐	- IF NO GO TO 10 - IF YES STOP - SE
8. NEW TYPES OF SAFETY OR EFFECTIVENESS QUESTIONS?	☐	☐	- IF YES STOP - NE
9. ACCEPTED SCIENTIFIC METHODS EXIST?	☐	☐	- IF NO STOP - NE
10. PERFORMANCE DATA AVAILABLE?	x	☐	- IF NO REQUEST DATA
11. DATA DEMONSTRATE EQUIVALENCE?	x	☐	

NOTE: IN ADDITION TO COMPLETING PAGE TWO, "YES" RESPONSES TO QUESTIONS 4, 6, 8, AND 11, AND EVERY "NO" RESPONSE REQUIRES AN EXPLANATION ON PAGE THREE AND/OR FOUR.

NARRATIVE DEVICE DESCRIPTION

1. INTENDED USE: The BioSorbFX Orthognathic and Mandibular (O/M) Bioabsorbable Fixation System is intended for use in trauma and reconstructive procedures in the midface, maxilla and mandible. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the midface, maxilla and mandible, and in orthognathic and reconstructive procedures of the midface, maxilla or mandible. The BioSorbFX O/M System stabilizes bone during healing in conjunction with appropriate postoperative immobilization. The BioSorbFX O/M System is not intended for use in and is contraindicated for: 1) mandibular tumor resection; 2) significant comminuted fractures, including significant bone loss, of the mandible and 3) intermaxillary fixation.

2. DEVICE DESCRIPTION: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. The following should be considered when preparing the summary of the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the devices design, materials, physical properties and toxicology profile if important.

SUMMARY:

The BioSorbFX O/M System is a system of bone plate and mesh configurations affixed to bone by 2.0 mm and 2.4 mm screws. The system also includes a 2.8 mm emergency screw and accessory instrumentation for implantation of the screws. The 2.0 mm screw has a minor (shaft) diameter of 1.45 mm and is available in lengths of 4, 6, 8, 10, 12, 14, 16, 18, 20 ,24, 28, 32, 36 and 40 mm. The 2.4 mm screw has a minor diameter of 1.55 mm and is provided in lengths in 6, 8, 10, 12, 14, 16, 18, 20 ,24, 28, 32, 36 and 40 mm. The 2.8 mm emergency screw has a minor diameter of 1.95mm and lengths of 6, 8, 10, 12, 14, 16, 18, 20 ,24, 28, 32, 36 and 40 mm. The 2.8 mm screw is intended to serve as an emergency screw for the 2.4 mm screw and the 2.4 mm screw can be used as an emergency screw for the 2.0 mm screw. The accessory instrumentation set contains bone drills, bone taps, a screwdriver and a plate bender. It is equivalent to the instrumentation set that is a part of the Bionx BioSorb Endobrow Screw. The only difference is that the components have been resized to correspond to the sizes of the screws and the plate bender has been added to the set. The accessory instruments are fabricated from stainless steel (400 series).

The bone plates will be available in 1.2 mm and 1.4 mm thick plates of various shapes. It should also be noted that the thickness of the mesh plates is 1 mm rather than 1.2 or 1.4 mm. The bone plates may be cut or bent at room temperature with being heated. The BioSorbFX O/M

System stabilizes bone during healing in conjunction with postoperative immobilization. The system also includes 5x5 hole and 5x10 hole rectangular meshes. The BioSorbFX O/M System will be provided sterile and pyrogen free. The components are to be sterilized via gamma radiation.

The components of the system are made from poly-L/DL-lactide {P(L/DL)LA} copolymer. This material has been used for other Bionx, Inc. predicate implant devices such as the Biodegradable Threaded Suture Anchor (K972783) and the BioSorb Endobrow Screw (K972919). The LactoSorb® Trauma Plating System, by Walter Lorenz Surgical, Inc., is also made from a bioabsorbable polylactide material. Bionx, Inc. has referenced the FDA Master File 357 for this material that was submitted by Boehringer Ingleheim; the Bionx product is the same as that described in MAF 357. The P(L/DL)LA copolymer is a bioabsorbable polylactide polymer that degrades within 2 to 3 years postoperatively; the material is generally completely resorbed in 4 years.

The P(L/DL)LA copolymer is a blend of 70 molar percent L-lactide and 30 molar percent D,L-lactide and maintains its strength for 12 to 22 weeks. This is longer than the healing periods generally required for the device's indications for use. The P(L/DL)LA copolymer is a self-reinforced copolymer, while the LactoSorb® is made of a synthetic polyester consisting of lactic and glycolic acids (PLA/PGA). The P(L/DL)LA copolymer degrades *in vivo* by hydrolysis into lactate and glutate monomers. L-lactate, the major conformation of lactic acid found in mammals, can be oxidized to form pyruvate, which is used in glucose synthesis or is metabolized into carbon dioxide and water.

Details regarding the chemical composition of the P(L/DL)LA copolymer were provided. The polymer contains less than 5 ppm of chromium, cobalt, manganese, molybedenum and tin and less than 20 ppm of aluminum, nickel, silicon and iron. Acetone is used as a solvent for processing the raw material. The final level of solvent contained in the product after processing the plates and fasteners is less than 0.1 wt% of the residue, toluene. The monomer content of P(L/DL)LA is less than 0.5%. The average molecular weight of the raw material is 260,000 - 430,000 Daltons (D) and the intrinsic viscosity of 5 - 7dl/g. The molecular weight of the finished product ranges from 35,000 - 65,000 D with an intrinsic viscosity of 1.1 to 1.8 dl/g. The copolymer is amorphous. The polymer matrix is reinforced with P(L/DL)LA fibers that are oriented axially. The surface of the BioSorbFX O/M System plates is smooth, with an average roughness (R_a) of 2 - 8 μm.

The BioSorbFX O/M System is sold sterile and is for single use only. The devices are sterilized by gamma irradiation with a minimum dose of 25 kGy. The SAL is 10^{-6}. Each plate is packaged in an individual paper board holder. One to six screws are packaged in a paper board holder. Both the plates and screws are sealed in an aluminum foil pouch, which is then sealed in a Tyvek® pouch and placed in cardboard boxes. In case the device is accidentally contaminated by the user prior to insertion, the device is not to be resterilized by the user. After sterilization, samples from each lot are subjected to final

testing to validate conformance to specifications for sterility, mechanical strength and packaging integrity.

Animal and clinical studies have shown that the resorption rate is such that accumulation of the by-products of P(L/DL)LA hydrolysis is not sufficient to affect the blood pH levels.

SUMMARY OF CLINICAL STUDIES

Clinical Study of Bionx BioSorbFX O/M P(L/DL)LA 2.0-2.4 mm Fixation System for Orthognathic Surgery:

- Treatment: bimaxillary surgery
- Sample size: 10 patients (5 female, 5 male)
- Age range: 17 - 33 (average age: 22)
- Exclusions: patients with congenital deformities, local or systemic diseases or a history of maxillofacial trauma
- Surgical procedures: bimaxillary surgery and genioplasty
- Devices used: 1.2 mm plates and 2.0 mm screws
- Total number of devices used: 62 plates, 40 in the maxilla, 20 in the mandible and 2 in the chin; 305 screws
- Patients were followed for 6 weeks and 3 months postoperatively; seven patients were evaluated at the 3 month postoperative time point
- Results:
  - None of plates broke during bending for surgical placement, although internal delamination occurred as evidenced by opaque lines in the bent areas; the plates were able to function with sufficient strength and stability
  - 293 (96.1%) of 305 screws used had good fit; the slits in the screw head of 18 of these were damaged at the last twist, but this did not influence the fit in the bone
  - No cases of delayed bone union
  - At six weeks, all operate jaws clinically stable
  - At six weeks, no evidence of chronic inflammatory reaction, wound dehiscence or plate exposure
  - Six weeks postoperatively, occlusion was stable; there was no need to remove plates and screws because of malocclusion in any case
  - There were minimal changes in the occlusion between the six week and three month postoperative periods
  - The short term stability appeared to be better when compared to wire osteosynthesis and similar to the results of metal devices
- Adverse events:

- One patient developed an infection three weeks postoperatively, which resolved after intraoral incision and antibiotics
- Twelve screws deficient in their fit: 6 screwheads broke off before full insertion; 6 screws had an insufficient fit; the screws were either replaced or holes drilled through the screw and a new screw inserted; there were no other adverse effects resulting from these screw failures

The remainder of the clinical information provided is based on data from clinical studies in which PLLA bone plates and/or screws were used for mandibular fixation. Animal studies were also submitted for both PLLA bone plates and screws. One animal study using the P(L/DL)LA bone plates and screws in the mandibles of sheep was submitted.

ANALYSIS:

The material used for this device appears to be well characterized chemically and in terms of toxicological biocompatibility. As stated by the company, the material has been used for several other bone fixation devices. In addition, the BioSorbFX 1.5/2.0 Bioabsorbable Fixation System was also recently cleared under K982139. This fixation system is similar to the present device except the screw hole size, the corresponding screw size and the indications for use of the device. The BioSorbFX 1.5/2.0 Bioabsorbable Fixation System is intended for midface and maxillary indications only. It is specifically contraindicated for mandibular use.

The BioSorbFX 2.0/2.4 O/M System is indicated for both midface/maxillary indications and mandibular indications. Sufficient biocompatibility information and mechanical strength retention information has been provided for the midface/maxillary indications. However, additional information was requested for the mandibular indication.

In response to the additional information requested regarding the mandibular indication, the sponsor has decided to remove this indication from the labeling. Additional information items 1, 2, and 3 were in reference to the mandibular indication; therefore, the information requested in these items is no longer necessary at this time. The applicant only seeks clearance for the midface and maxillary indication.

Based on the engineering drawings, it appeared as though the mesh plates receive a smaller screw. The applicant was asked to clarify the screw that is to be used with the mesh plates. It appears as though the 1.5 mm screw previously cleared in K982139 is to be used with the mesh plates. The applicant confirmed this by phone on February 16, 1999.

In a phone call to the company's consultant on December 24, 1998, the company was asked to explain the use and need for the longer screw lengths (i.e., those lengths above 28 mm) in midface and maxillary indications. They were also asked, in a subsequent telephone conversation, whether or not any testing had been performed on the longer screw lengths. The applicant responded that they would limit the screw lengths to the following.

Diameter (mm)	Lengths (mm)
2.0 mm	**4, 6, 8, 10, 12, 14, 16, 18**
2.4 mm	**4, 6, 8, 10, 12, 14, 16, 18, 20 ,24**
2.8 mm	**4, 6, 8, 10, 12, 14, 16, 18, 20 ,24**

The 2.0 mm screw has the same length range as that of the previously cleared BioSorbFX 1.5/2.0 Bioabsorbable Fixation System. The applicant clarified that the bending and shear strength retention tests results previously submitted were performed on the 2.4 x 40 mm and 2.8 x 40 mm screws. In addition, torsional testing was performed on the 2.4 x 20 mm and 2.8 x 20 mm screws. The pull-out testing was performed on the 2.0 x 10 mm, 2.4 x 12 mm and the 2.8 x 12 mm screws. The results of this testing is acceptable.

RECOMMENDATION

The BioSorbFX 2.0/2.4 Orthognathic Bioabsorbable Fixation System may be found substantially equivalent to other bioabsorbable fixation plating systems.

P. D. Scott 2/16/99

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 1999

Bionx Implants, Incorporated
C/O Mr. Jonathan S. Kahan
Hogan & Hartson
Columbia Square
555 Thirteenth Street, NW
Washington, D.C. 20004-1109

Re: K982721
Trade Name: BioSorbFX 2.0/2.4 Orthognathic and Mandibular Bioabsorbable Fixation System
Regulatory Class: II
Product Code: JEY
Dated: November 19, 1998
Received: November 19, 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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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" (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): K982721

Device Name: BioSorbFX 2.0/2.4 Bioabsorbable Fixation System

Indications for Use: The BioSorbFX 2.0/2.4 Bioabsorbable Fixation System ("BioSorbFX 2.0/2.4 System") is intended for use in trauma and reconstructive procedures in the midface and maxilla. Specifically, the device is indicated for use in surgical repair procedures in the treatment of trauma to the midface and maxilla, and in orthognathic and reconstructive procedures of the midface or maxilla. An instrumentation set which is used to implant the fasteners to secure the plates to bone is included with the BioSorbFX 2.0/2.4 System. The BioSorbFX 2.0/2.4 System is not intended for use in mandibular applications.

(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 Dental, Infection Control, and General Hospital Devices

Prescription Use ✓ OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K982721

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