

MAR 20 1998

K97 4876

**510(K) SUMMARY FOR THE BIONX IMPLANTS, INC.**

**BIODEGRADABLE, THREADED DISTAL RADIUS SCREW**

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

Bionx Implants, Inc.  
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Gwynedd Hall Suite 400  
Bluebell, PA 19422

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President and CEO  
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**Date Prepared**

March 13, 1998

**Name of the Device**

Bionx Biodegradable, Threaded Distal Radius Screw

**Common or Usual Name**

Bionx Distal Radius Screw

**Classification Name**

Bone Screw (87 HWC)

**Predicate Devices**

- 1) Zimmer, Inc. Herbert Bone Screw (K792022) ("Herbert Bone Screw")
- 2) Synthes Dorsal Distal Radius Plate System (K962616) ("Synthes Dorsal Plate")
- 3) Synthes Volar Distal Radius Plate (K953644) ("Synthes Volar Plate")
- 4) Zimmer, Inc. Forte Distal Radius Plate (K953714) ("Zimmer Forte Plate")

## 5) Synthes Polypin (K961608)

### **Intended Use**

The Bionx Distal Radius Screw is intended for use in the fixation of cancellous bone fractures in combination with appropriate postoperative cast immobilization. The device will specifically be indicated for use in open reduction and internal fixation of Frykman type I - IV dorsally displaced Colles fractures, osteotomies, and carpal fusions of the distal radius. All of the predicate devices are intended for use in the fixation of cancellous bone fractures, and all are specifically indicated for use in radial fractures.

### **Principles of Operation**

The Bionx Distal Radius Screw is a fully threaded, cylindrical, cannulated screw which is 4.5 mm in outer diameter. The screw threads secure the screw in the bone throughout the healing period, after which the screw gradually degrades and is completely absorbed by the body. Thus, there is no need to surgically remove the device.

### **Technical Characteristics**

The Bionx Distal Radius Screw, the Herbert Bone Screw, the Synthes Dorsal Plate, the Synthes Volar Plate, the Zimmer Forte Plate, and the Synthes Polypin all possess similar technical characteristics. The Bionx Distal Radius Screw, the Herbert Bone Screw, and the Synthes Polypin are screw type devices, while the other predicates are plate type devices. However, this difference in configuration does not raise any new questions of safety or effectiveness because the

devices incorporate similar features (i.e., threaded screws or concentric, ring-shaped ribs) to ensure that they remain fixed in the bone. In addition, although the Bionx Distal Radius Screw is made of biodegradable poly-L-lactide polymer, while the Synthes Polypin is composed of poly-(L/DL)-lactide polymer, and the other predicate devices are composed of titanium or stainless steel, this difference in materials does not raise any new questions of safety or effectiveness. The poly-L-lactide polymer used in the Bionx Distal Radius Screw is the same material that has been used in other previously cleared implantable devices. Moreover, the biocompatibility all of these materials has been established in the medical literature, and all of the materials possess sufficient strength for distal radius fixation. Clinical testing and performance testing have also demonstrated the safety and effectiveness of the Bionx Distal Radius Screw for this intended use.

#### **Summary Basis for the Finding of Substantial Equivalence**

Like the previously cleared Herbert Bone Screw, the Synthes Dorsal Plate, Synthes Volar Plate, Zimmer Forte Plate, and Synthes Polypin, the Bionx Distal Radius Screw is intended for use in fixation of cancellous bone fractures, and specifically indicated for use in the fixation of radial fractures. Furthermore, 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 or materials, do not raise new questions of safety or effectiveness, as confirmed by clinical and mechanical testing. Thus, the devices are substantially equivalent.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

MAR 20 1998

Jonathan S. Kahan, Esq.  
Hogan & Hartson L.L.P.  
Representing Bionx Implants, Inc.  
555 Thirteenth Street, NW  
Washington, DC 20004-1109

Re: K974876  
Trade Name: Biodegradable, Threaded Distal Radius Screw  
Regulatory Class: II  
Product Codes: MAI and HWC  
Dated: December 24, 1997  
Received: December 29, 1997

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.

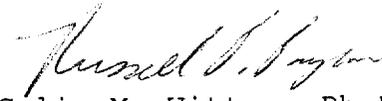
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the 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.

Page 2 - Jonathan S. Kahan, Esq.

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): K974876

Device Name: Bionx Biodegradable Threaded Distal Radius Screw

Indications For Use:

The Bionx Biodegradable, Threaded Distal Radius Screw is intended for use in the fixation of cancellous bone fractures in combination with appropriate postoperative cast immobilization. The device will specifically be indicated for use in open reduction and internal fixation of Frykman type I - IV dorsally displaced Colles fractures, osteotomies, and carpal fusions of the distal radius.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Russell J. Kozom* for CDRH

(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K974876

Prescription Use   
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)