K992947

SEP 21 1999

510(k) Summary

Bionx Implants Inc.

Cannulated SmartScrew™

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

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

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President and Chief Operating Officer
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Regulatory Affairs Assistant
P.O.Box 3
FIN-33721 Tampere
Finland
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Date prepared: August 17th, 1999

Name of the device:

A. Trade or Proprietary Name: Cannulated SmartScrew™

B.	Common Name:	Bionx Bioabsorbable Cannulated, Threaded, Fixation Rod
C.	Classification Name:	Biodegradable fixation fastener, bone
D.	Device Product Code:	HWC

Predicate Devices:

Bionx Implants Inc. Biofix® Bioabsorbable SR-PLLA Threaded Fixation Rod (K952471)
Bionx Implants Inc. Biofix® Bioabsorbable, Threaded, Distal Radius Screw (K974876)

Intended Use:

The Cannulated SmartScrew™ is intended for maintenance of alignment of cancellous fractures of the malleolus of the ankle in the presence of appropriate immobilization. In conjunction with adequate surgical technique and postoperative immobilization, the Cannulated SmartScrew™ provides secure fixation and will maintain sufficient physical integrity and mechanical holding properties within the bone, well beyond the five to eight weeks needed for complete biological healing and realignment of the fixation site.

Device Description:

The Cannulated SmartScrew™ is composed of 100% poly-L-lactide ("PLLA") polymer. It is supplied with diameter 4.5mm and lengths 40, 45, 50, 55, 60, 65, 70mm. It is cannulated for 1.5mm K-wire.

Substantial Equivalence:

The Bionx Cannulated SmartScrew™ has the following similarities to the Bionx Biofix® Bioabsorbable SR-PLLA Threaded Fixation Rod (K952471):

- has the same indicated use
- use the same operating principle
- incorporate the same basic design
- incorporate the same raw material
- has the same shelf life
- are packaged and sterilized using the same materials and processes

The Bionx Cannulated SmartScrew™ has the following similarities to the Bionx Biofix® Bioabsorbable, Threaded, Distal Radius Screw (K974876):

- use the same manufacturing process
- is used with the same instrument set

In summary, the Cannulated SmartScrew™ described in this notification is, in our opinion, substantially equivalent to the predicate devices. Furthermore, the minor technological differences between the Cannulated SmartScrew™ 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 21 1999

Ms. Tuija Annala
Regulatory Affairs Assistant
Bionx Implants Ltd.
Hermiankatu 6-8 L
Tampere, Finland
Europe

Re: K992947
Trade Name: Cannulated SmartScrew ™
Regulatory Class: II
Product Code: HWC and MAI
Dated: August 17, 1999
Received: September 1, 1999

Dear Ms. Annala:

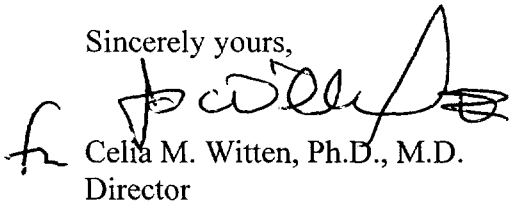
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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 at (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

INDICATIONS FOR USE

510(K) Number (if known): K992947

Device Name: Cannulated SmartScrew™

Indications for Use:

Cannulated SmartScrew™ is intended for maintenance of alignment of cancellous fractures of the malleolus of the ankle in the presence of appropriate immobilization. In conjunction with adequate surgical technique and postoperative immobilization, the Cannulated SmartScrew™ provides secure fixation and will maintain sufficient physical integrity and mechanical holding properties within the bone, well beyond the five to eight weeks needed for complete biological healing and realignment of the fixation site.

The Cannulated SmartScrew™ is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (diaphyseal area), 2) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism).

(Please do not write below this line – continue on another page is needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992947