K012001

JUL 1 8 2001

510(k) Summary
Bionx Implants Inc.
SmartScrew™

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

Bionx Implants, Inc.
1777 Sentry Parkway West
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Bluebell, PA 19422

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Bionx Implants Ltd.
Tuija Annala
Director, Quality and Regulatory Affairs
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5629

Date prepared: June 13, 2001

Name of the device:

A.	Trade or Proprietary Name:	SmartScrew™
B.	Common Name:	Bioabsorbable, 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, K992947)
Bionx Implants Inc. SmartScrew™ (K003077)

Intended Use:

The SmartScrew™ is generally intended for maintenance of alignment and fixation of fractures, osteotomies, arthrodeses or condylar grafts within the condylar aspects of the upper extremity, ankle and foot, in the presence of appropriate brace and/or immobilization. Specifically, it is intended for phalangeal fusion and fracture, metacarpal fusion and fracture, carpal fusion and fracture, wrist arthrodesis, Distal radius fractures, olecranon fractures, radial head fractures, humeral condylar fractures, cancellous fractures and osteotomies of the malleolus, ankle fractures, metatarsal osteotomies and correction of hallux valgus.

The SmartScrew™ is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except those in the hand and foot) and proximal femoral fractures, 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).

Device Description:

The SmartScrew™ is composed of poly-L,D-lactide copolymer. It is supplied fully threaded with diameters 2.0mm – 4.5mm and lengths 10 - 70mm.

Substantial Equivalence:

The SmartScrew™ has the following similarities to the Bionx Implants The new SmartScrew™ has the following similarities to the cleared SmartScrew (K003077):

- has the same indicated use
- uses the same operating principle
- incorporates the same basic design of thread
- utilizes the same basic dimensions
- is packaged and sterilized using the same materials and processes
- has the same shelf life
- has the same trade name

The predicate device is the Bionx Implants Inc. SmartScrew™ (K952471, K974876, K992947, K003077). These devices have very similar principles of operation and technological characteristics.

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

JUL 1 8 2001

Ms. Tuija Annala
Director, Quality and Regulatory Affairs
Bionx Implants, Ltd.
P.O. Box 3
Hermiankatu 6-8L
FIN-33721 Tampere
Finland

Re: K012001
Trade Name: SmartScrew™
Regulation Number: 888.3040
Regulatory Class: II
Product Codes: HWC and MAI
Dated: June 14, 2001
Received: June 27, 2001

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 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) 594-4659. 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" (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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K012001

Device Name: SmartScrew™

Indications for Use:

The SmartScrew™ is generally intended for maintenance of alignment and fixation of fractures, osteotomies, arthrodeses or condylar grafts within the condylar aspects of the upper extremity, ankle and foot, in the presence of appropriate brace and/or immobilization. Specifically, it is intended for phalangeal fusion and fracture, metacarpal fusion and fracture, carpal fusion and fracture, wrist arthrodesis, Distal radius fractures, olecranon fractures, radial head fractures, humeral condylar fractures, cancellous fractures and osteotomies of the malleolus, ankle fractures, metatarsal osteotomies and correction of hallux valgus.

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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)

Do not check this box

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

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