K993073
1 of 2

DEC - 6 1999

510(k) Summary
Bionx Implants Inc.
SmartScrew ACL™

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.
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P.O.Box 3
FIN-33721 Tampere
Finland
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Date prepared: August 24th, 1999

Name of the device:

A.	Trade or Proprietary Name:	SmartScrew ACL™
B.	Common Name:	Bioabsorbable Interference Screw
C.	Classification Name:	Biodegradable fixation fastener, bone and soft tissue
D.	Device Product Code:	HWC and MAI

Predicate Devices:

DePuy, Inc.	Phantom PLLA Interference Screw (K955733) Resorbable Interference Screw (K981670) Phantom Resorbable Interference Screw (K982662)
Linvatec Corporation	BioScrew Fixation System (K933719, K952831, K973758)
Instrument Makar, Biomet, Inc.	Biologically Quiet Interference Screw (K943249) Arthrotek Interference Screw (K982496)

Arthrex, Inc.	The Arthrex Bio-Interference Screw (K971358)
Tornier S.A	Phusis Absorbable Interference Screw (K970829)
Acufex Microsurgical,Inc	Acufex Endofix Absorbable Interference Screw (K954246)
Smith and Nephew, Inc.	Bioabsorbable Interference Screw (K984320)
Sulzer Orthopedics, Inc.	Sysorb Interference Screw (983592)

Intended Use:
The SmartScrew ACL™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions.

Device Description:

The SmartScrew ACL™ a fully threaded, cannulated interference screw with slightly tapered head and tip. SmartScrew ACL™ is provided with three different diameter, 7.0, 8.0 and 9.0mm and with three lengths, 20, 25 and 30mm and it is made of poly-L/D-lactide copolymer.

Substantial Equivalence:

The SmartScrew ACL™ has the same intended use, principles of operation and technological characteristics than predicate devices.

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

DEC -6 1999

Mrs. Tuija Annala
Regulatory Affairs Assistant
Bionx Implants Limited
P.O. Box 3
FIN-33721 Tampere
Finland

Re: K993073
Trade Name: SmartScrew ACL™ Bioabsorbable Interference Screw
Regulatory Class: II
Product Codes: MAI and HWC
Dated: August 23, 1999
Received: September 14, 1999

Dear Mrs. 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 (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Neil R P Ogden for

James E. Dillard III
Acting 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): K993073

Device Name: SmartScrew ACL™

Indications for Use:

The SmartScrew ACL™ is intended for use in interference fixation of bone-patellar tendon – bone and soft tissue grafts in anterior and posterior cruciate ligament reconstructions.

The SmartScrew ACL™ is not intended for use in and is contraindicated for 1) cruciate ligament reconstructions, which would not be appropriate for fixation with metallic screws and 2) situations, where intra-articular replacement is otherwise contraindicated, e.g., active or potential infection and where patient cooperation cannot be guaranteed (e.g., alcoholism).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

NRO for

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993073