

510(k) Summary
Bionx Implants Inc.
SmartNail™

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

Bionx Implants, Inc.
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Bionx Implants Ltd.
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P.O.Box 3
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Finland
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Date prepared: September 2nd, 1999

Name of the device:

- A. Trade or Proprietary Name: SmartNail™
- B. Common Name: Absorbable Bone Fixation Nail
- C. Classification Name: Bone Fixation Nail
- D. Device Product Code: JDS

Predicate Devices:

1. Bionx Implants, Inc. Biofix® SR-PGA Pin (K890902)
2. Bionx Implants Inc. SmartPin™ (K925098)
3. Johnson & Johnson Orthopedics, Inc. Orthosorb Absorbable Pin (K864912, K882979, K901456)
4. Synthes Inc. Polypin (K961608)

Intended Use:

Properly used, in the presence of adequate immobilization, absorbable SmartNail™ is intended for use in the fixation of fragments of fractured non-load bearing bones, osteotomies and arthrodeses, for example in the fixation of apical fragments, osteochondral fragments and cancellous/non-load bearing fragments. The SmartNail™ includes an arthroscopic applicator set. The arthroscopic applicator set consists of Handle, Tip, Piston, House, Wrench, Drill bit and K-wires.

The SmartNail™ is not intended for use in and is contraindicated for: 1) Fractures and osteotomies of cortical bone (except cortical bones of the foot and the hand), 2) Fractures and osteotomies in weight bearing cancellous bone, 3) Situations where internal fixation is otherwise contraindicated, e.g., active or potential infection and where patient co-operation cannot be guaranteed (e.g. alcoholism), 4) Treatment of physeal fractures in children, because the effect of SmartNail™ upon the healing of growth plate has not been tested clinically.

Device Description:

The SmartNail™ is provided with a diameter of 1.5 mm and lengths of 16, 20 and 25 mm. 5 barbs, placed at intervals of 1.5 mm on two sides of the SmartNail™, prevent the implanted SmartNail™ from slipping out. The SmartNail™ is made of polylactide homopolymer and polylactide copolymer materials with strength retention time 20-50 weeks.

Substantial Equivalence:

Bionx Implants Inc. SmartNail™ is substantially equivalent to the cleared Bionx Implants Inc. Biofix® SR-PGA Pin (K890902) and SmartPin™ (K925098), Johnson & Johnson Orthopedics, Inc. Orthosorb Absorbable Pin (K864912, K882979, K901456) and Synthes Inc. Polypin (K961608). The SmartNail™, Biofix® SR-PGA Pin (K890902), Orthosorb® (K864912, K882979, K901456) and Synthes Polypin (K961608) have the same intended use and principles of operation and very similar technological characteristics.

Furthermore, the minor technological differences between the Bionx Implants Inc. SmartNail™ and the predicate devices do not raise any new issues of safety or effectiveness.



DEC 10 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

Re: K993074
Trade Name: SmartNail
Regulatory Class: II
Product Code: MAI
Dated: September 3, 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.

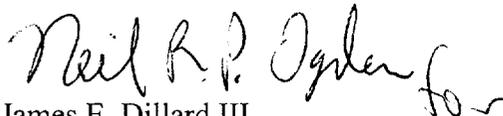
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

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 at (301) 443-6597, or at its Internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



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): K993074

Device Name: SmartNail™

Indications for Use:

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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)

Russell P. Kagan for J20
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993074