NOV - 9 1999

K993453

# 510(k) Summary
# Bionx Implants Inc.
# Meniscus Arrow™

**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
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Bionx Implants Ltd.
Tuija Annala
Regulatory Affairs Assistant
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5688


**Date prepared:** September 17th, 1999

**Name of the device:**

| | | |
|---|---|---|
| A. | Trade or Proprietary Name: | Meniscus Arrow™ |
| B. | Common Name: | Bioabsorbable Meniscus Arrow System |
| C. | Classification Name: | Biodegradable soft tissue fixation fastener |
| D. | Device Product Code: | MAI |

**Predicate Device:**

Bionx Implants Inc. Biofix® Biodegradable Meniscus Arrow System (K955768)

**Intended Use:**

The Meniscus Arrow™ is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascular area of the meniscus (e.g. "red-red" and "red-white" zones) in conjunction with immobilization during healing.

The principles of operation remain, but the Meniscus Arrow™ Inserter, so called Crossbow®, simplifies the procedure. The previous piston was used mounted on a reciprocating instrument run by air pressure, electricity or the implant was manually hammered into the meniscus. Among these possibilities we now offer the opportunity to use our modified Meniscus Arrow™ Inserter, Crossbow®, which is a manual, spring-powered instrument and there is no need to connect it to air pressure or electricity.

**Device Description:**

The device description of the Meniscus Arrow™ is as follows.
- Composed of poly-L/D-polylactide copolymer
- Length 10, 13 and 16mm
- Diameter 1.1mm

The dimensions and shape are completely identical with the Biofix® Biodegradable Meniscus Arrow System (K955768).

**Substantial Equivalence:**

The Meniscus Arrow™ has the following similarities to the cleared Biofix® Biodegradable Meniscus Arrow System (K955768):

- has the same indicated use
- use the same operating principle
- incorporate the same basic design
- is manufactured by same machinery
- is packaged and sterilized using the same materials and processes
- has the same shelf life
- are packaged and sterilized using the same materials and processes
- has the same trade name

In summary, the Meniscus Arrow™ described is substantially equivalent to the predicate device. This change of raw material does not raise any problems concerning safety or efficacy of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV - 9 1999

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

Re: K993453
Trade Name: Biofix® Biodegradable Meniscus Arrow™ System
Regulatory Class: II
Product Code: MAI
Dated: September 17, 1999
Received: October 13, 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,

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

## INDICATIONS FOR USE

**510(K) Number (if known):** K993453

**Device Name:** Meniscus Arrow™

**Indications for Use:**

The Meniscus Arrow™ is intended for arthroscopic fixation of longitudinal vertical meniscus lesions (bucket-handle) located in the vascular area of the meniscus (e.g. "red-red" and "red-white" zones) in conjunction with immobilization during healing.

(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)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993453