K003970

JAN 1 2 2001

510(k) Summary
Bionx Implants Inc.
Contour Labral Nail™

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

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

Contacts: Gerard S. Carlozzi
President, CEO
Phone: (215) 643-5000
Facsimile: (215) 653-0984

Bionx Implants Ltd.
Tuija Annala
Quality Manager
P.O.Box 3
FIN-33721 Tampere
Finland
Phone: 358-3-316 5679
Facsimile: 358-3-316 5688

Date prepared: December 14th, 2000

Name of the device:

A. Trade or Proprietary Name: Contour Labral Nail™

B.	Common Name:	Bionx Contour Labral Nail
C.	Classification Name:	Biodegradable soft tissue fixation fasteners
D.	Device Product Code:	87 MAI

Predicate Device:

Bionx Implants Inc. Bankart Tack™ Biodegradable soft tissue fixation fastener (K973849) and Anatomical Bankart Tack™ (the current Contour Labral Nail™) Biodegradable soft tissue fixation fastener (K992567).

Intended Use:

The Contour Labral Nail™ is intended for use to maintain the proximity between soft tissue and bone to facilitate soft tissue reattachment in the repair of shoulder injuries. The Contour Labral Nail™ will be specifically indicated for use to provide internal fixation of soft tissue to bone for repair of anterior shoulder instability by reattachment of the glenoid labrum and/or inferior glenohumeral ligament in patients with primary or reoccurrent anterior dislocation or subluxation of the shoulder (*i.e.*, Bankart lesions).

Device Description:

The Contour Labral Nail™ is an absorbable device designed to maintain the proximity between soft tissue and bone to facilitate soft tissue reattachment in the repair of shoulder injuries. The Contour Labral Nail™ is composed of poly-L,D-lactide copolymer, its length is 20mm and diameter 3.5mm.

Substantial Equivalence:

The Contour Labral Nail™ is substantially equivalent to the cleared Bionx Bankart Tack™ (K973849) and Anatomical Bankart Tack™ (the current Contour Labral Nail™) (K992567). All three devices have the same intended use, similar principles of operation and technological characteristics. Furthermore, the minor technological differences between the Contour Labral Nail™ 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

JAN 1 2 2001

Bionx Implants, Inc.
Ms. Tuija Annala
Quality Manager
c/o Bionx Implants, LTD
Hermiankatu 6-8 L
Tampere,
Finland

Re: K003970
Trade Name: Contour Labral Nail™
Regulatory Class: II
Product Code: MAI, MNN and MRY
Dated: December 19, 2000
Received: December 22, 2000

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 control provisions of the Act. The general control 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,

Miriam C. Provost for

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

Enclosure

INDICATIONS FOR USE

510(K) Number (if known): K003970

Device Name: Contour Labral Nail™

Indications for Use:

The Bionx Contour Labral Nail™ is intended for use to maintain the proximity between soft tissue and bone to facilitate soft tissue reattachment in the repair of shoulder injuries. The Bionx Contour Labral Nail™ will be specifically indicated for use to provide internal fixation of soft tissue to bone for repair of anterior shoulder instability by reattachment of the glenoid labrum and/or inferior glenohumeral ligaments in patients with primary or recurrent anterior dislocation or subluxation of the shoulder (i.e. Bankart lesions).

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use_____

(Per 21 CFR 801.109)

Miriam C. Provost

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number K003970