



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

MAY 9 2005

Re: K003970

Trade/Device Name: Contour Labral Nail™

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and accessories

Regulatory Class: II

Product Code: MAI

Dated: December 19,2000

Received: December 22,2000

Dear Ms. Annala:

This letter corrects our substantially equivalent letter of January 12,2001 regarding the Contour Labral Nail™. This letter mistakenly listed MNN and MRY as product codes for your device. The only product code your device should be classified under is MAI (Fastener, Fixation, Biodegradable, Soft tissue).

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent 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) that do not require approval of a premarket approval (PMA). 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.

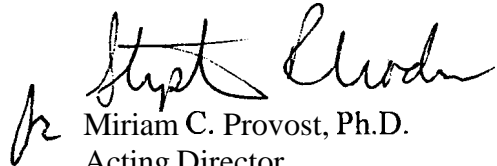
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-4369. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

A handwritten signature in black ink, appearing to read "Miriam C. Provost". The signature is written in a cursive style with a large initial "M" and "P".

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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

JAN 12 2001

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

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

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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 recurrent 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.