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NOV - 9 2006

510(k) SUMMARY for
Inion Anchron™ Plus Biodegradable Anchor System (K062782)

MANUFACTURER

Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person

Kati Marttinen, Regulatory Affairs Specialist
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DEVICE NAME

Trade name: Inion Anchron™ Plus Biodegradable Anchor System
Common/Usual Name: Suture anchor

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification Panel: Orthopedic
Regulation Number: 21 CFR 888.3030
Regulation Name: Fastener, fixation, biodegradable, soft tissue
Regulatory Class: Class II
Product Code: MAI

PREDICATE DEVICE

Inion Anchron™ Biodegradable Anchor System (K051362)

CONFORMANCE WITH PERFORMANCE STANDARDS

No applicable mandatory performance standards exist for this device.
Compliance to voluntary consensus standards is listed in the application.

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DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

Inion Anchron™ Plus Biodegradable Anchor System is intended to allow secure fixation of soft tissue to bone in conjunction with appropriate immobilization. The system consists of degradable suture anchor made of co-polymers PLDLA, non-degradable braided polyblend surgical suture with stainless steel needles, and a single-use suture anchor inserter. The suture anchors are dyed green. Based on in vitro testing: the suture anchors retain most of their strength up to 16 weeks and gradually loose their strength thereafter; and bioresorption takes place within three years.

Inion Anchron™ Plus Biodegradable Anchor system is provided sterile to the user. The shelf life of the device is 3 years.

INDICATIONS FOR USE

The INION ANCHRON™ PLUS BIODEGRADABLE ANCHOR SYSTEM is indicated for use in soft tissue to bone fixation in conjunction with appropriate post-operative immobilization as follows:

A. Open procedures:

1. Shoulder:
   - Bankart repair
   - SLAP lesion repair
   - Rotator cuff repair
   - Capsule shift/capsulo-labral reconstruction at the anterior glenoid rim site
   - Capsule shift/capsulo-labral reconstruction at the lesser tuberosity of the humerus
   - Biceps tenodesis
   - Acromio-clavicular separation

2. Elbow:
   - Biceps tendon reattachment

3. Ankle:
   - Achilles tendon repair/reconstruction
   - Lateral stabilization
   - Medial stabilization at the medial talus site

4. Knee:
   - Medial collateral ligament repair
   - Lateral collateral ligament repair
   - Joint capsule closure to anterior proximal tibia
   - Posterior oblique ligament or joint capsule to tibia repair
   - Extra capsular reconstruction / ITB tenodesis
   - Patellar ligament and tendon avulsion repairs

B. Arthroscopic procedures:

1. Shoulder:
   - Bankart repair
   - SLAP lesion repair
   - Rotator cuff repair
   - Capsule shift repair (glenoid rim)

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EQUIVALENCE TO MARKETED PRODUCTS

Based on the performance data and specifications presented, it can be concluded that the intended use, material composition and scientific technology, degradation profile and mechanical properties of the Inion Anchron™ Plus Biodegradable Anchor System are substantially equivalent with the predicate device Inion Anchron™ Biodegradable Anchor System (K051362).

Inion Anchron™ Plus Biodegradable Anchor System is substantially equivalent to predicate Class II devices used for secure fixation of soft tissue to bone in conjunction with appropriate immobilization, because the differences between Inion Anchron™ Plus Biodegradable Anchor System and the predicate device do not raise new questions of safety and effectiveness.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Inion Oy
% Ms. Kati Marttinen
Regulatory Affairs Specialist
Lääkärinkatu 2
FIN-33520 Tampere
FINLAND

NOV - 9 2006

Re: K062782
Trade/Device Name: Inion Anchron Plus Biodegradable Anchor System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI
Dated: October 20, 2006
Received: October 23, 2006

Dear Ms. Marttinen:

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 (for the indications for use stated in the enclosure) 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 application (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 such 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 begin 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) 276-0120. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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: K062782

Device Name: Inion ANCHRON™ PLUS Biodegradable Anchor System

The **INION ANCHRON™ PLUS BIODEGRADABLE ANCHOR SYSTEM** is indicated for use in soft tissue to bone fixation in conjunction with appropriate post-operative immobilization as follows:

A. Open procedures:

1. Shoulder:
   - Bankart repair
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   - Bankart repair
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   - Rotator cuff repair
   - Capsule shift repair (glenoid rim)

Prescription Use __X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Barbara Mechum for MKM Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of General, Restorative, and Neurological Devices

510(k) Number K062782