MAR 13 2006

SPECIAL 510(k) SUMMARY for the line extension of INION Hexalon ™ Biodegradable ACL/PCL Screw (K021280)

MANUFACTURER
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Contact Person
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DEVICE NAME
Trade name: Inion Hexalon™ Biodegradable ACL/PCL Screw
Common/Usual Name: Biodegradable Interference Screw
Classification Name: Bone Fixation Screw

ESTABLISHMENT REGISTRATION NUMBER
9710629

DEVICE CLASSIFICATION AND PRODUCT CODE
Classification panel: Orthopedic
Regulation number: 21 CFR 888.3040
Regulation name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC

PREDICATE DEVICE
Inion Hexalon™ Biodegradable ACL/PCL Screw (K021280)

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

THE REASON FOR SCPECIAL 510(k)
New screws to be added to Inion Hexalon™ Biodegradable ACL/PCL Screw (K021280).

INION
Intelligent Solution

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

Inion Hexalon™ Biodegradable ACL/PCL screws are intended to be used for interference fixation in anterior and posterior cruciate ligament reconstruction using bone-tendon-bone or soft tissue grafts.

The new screws are identical with the other implants in the previously 510(k) cleared Inion Hexalon™ Biodegradable ACL/PCL Screw (K021280) in terms of copolymer composition, colour additive, intended use and indications for use as described in the device labelling, manufacturing method and sterilization method.

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 new Inion Hexalon™ Biodegradable ACL/PCL screws are substantially equivalent with the predicate device Inion Hexalon™ Biodegradable ACL/PCL screw (K021280).

The new Inion Hexalon™ Biodegradable ACL/PCL screws are substantially equivalent to predicate Class II devices used for interference fixation in anterior and posterior cruciate ligament reconstruction using bone-tendon-bone or soft tissue grafts, because the differences between the new Inion Hexalon™ Biodegradable ACL/PCL screws and the predicate device do not raise new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 13 2006

Inion Limited
c/o Ms. Hanna Marttila
Regulatory Affairs Director
Laakarinkatu 2
Fin-33520 Tampere
Finland

Re: K060393
Trade/Device Name: Inion Hexalon™ Biodegradable ACL/PCL Screw
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: February 13, 2006
Received: February 15, 2006

Dear Ms. Marttila:

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

Sincerely yours,

for Mark N. Melkerson
Acting 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: K060393

Device Name: **Inion Hexalon™ Biodegradable ACL/PCL Screw**

Indications:

The **INION HEXALON™ BIODEGRADABLE ACL/PCL SCREW** is intended for interference fixation in anterior and posterior cruciate ligament reconstruction using bone-tendon-bone or soft tissue grafts.

Contraindications:

The **INION HEXALON™ BIODEGRADABLE ACL/PCL SCREW** is contraindicated in case of:

1. Insufficient quality or quantity of bone for interference screw attachment
2. Active or potential infections
3. Patient conditions including limited blood supply, chronic disease which causes insufficient quality of bone, and where patient cooperation cannot be guaranteed (e.g. alcoholism, drug abuse)

Prescription Use Yes (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use No (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K060393