510(k) SUMMARY

Inion Spinal Graft Containment System

Manufacturer and submitter
Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person
Kati Marttinen, Regulatory Affairs Specialist
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Establishment registration number
9710629

Trade name of the device
Inion Spinal Graft Containment System

Device classification and product code
Class II
Classification Panel: Orthopedic
Product Code: KWQ
Common name: Appliance, fixation, spinal intervertebral body
Regulation number: 21 CFR 888.3060

Predicate devices
Macropore OS Spine™ System (K010911)
MacroPore Hydrosorb™ Spine System (K041105)
Inion S-1™ Biodegradable Anterior Cervical Fusion System (K051821)
Biomet Tantalum Beads – Radiographic Marker (K010348)

Device description and principles of operation

Inion Spinal Graft Containment System includes plates, meshes and screws which are made of degradable polylactic acid copolymers, P(L/DL)LA. Based on in vitro data: the implants retain most of their initial strength 16 weeks and gradually lose their strength thereafter. Bioresorption takes place within two to four years. The plates and screws include tantalum spheres for postoperative radiographic imaging.

The implants are offered in different shapes and sizes suitable for this application. Inion Spinal Graft Containment System implants are provided sterile to the user and are non-collagenous. The shelf life of the device is 3 years.

INION
Intelligent Solution

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Inion Spinal Graft Containment System

Indications for use

Inion Spinal Graft Containment System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Substantial 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 Inion Spinal Graft Containment System are substantially equivalent with the predicate devices Macropore OS Spine™ System (K010911), MacroPore Hydrosorb™ Spine System (K041105) and Inion S-1™ Biodegradable Anterior Cervical Fusion System (K051821), and additionally in regard to radiographic marker, with Biomet Tantalum Beads – Radiographic Marker (K010348).

Inion Spinal Graft Containment System is substantially equivalent to predicate Class II devices when used, in conjunction with traditional rigid fixation, in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts, because the differences between Inion Spinal Graft Containment System and the predicate devices 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

JUL 1 1 2008

Inion Oy
% Ms. Kati Marttinen
Regulatory Affairs Specialist
Laakarinkatu 2
Tampere
Finland 33520

Re: K071810
Trade/Device Name: Inion Spinal Graft Containment System
Regulation Number: 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: OJB
Dated: April 21, 2008
Received: April 24, 2008

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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Precautions/Warnings section of the device's labeling:

> "The safety and effectiveness of this device, as an adjunct to fusion, when used without rigid supplemental internal fixation has not been established. This device is not designed to withstand physiologic loads when used by itself."

Furthermore, the indication for graft containment use must be prominently displayed in all labeling, including pouch box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

If you desire specific information about the application of other labeling requirements to your device (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" (21 CFR 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,

Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K071810

Device Name: Inion Spinal Graft Containment System

Indications For Use:

Inion Spinal Graft Containment System, in conjunction with traditional rigid fixation, is intended for use in spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts or autografts. The device is not intended for load bearing indications.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)