NOV 25 2005

510(k) SUMMARY for Inion S-1™ Biodegradable Anterior Cervical Fusion System

MANUFACTURER

Inion Ltd., Lääkärinkatu 2, FIN-33520 Tampere, FINLAND

Contact Person

Hanna Marttila, Regulatory Affairs Director
Lääkärinkatu 2, FIN-33520 Tampere
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DEVICE NAME

Trade name: Inion S-1™ Biodegradable Anterior Cervical Fusion System

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Class : II
Classification Panel: Orthopedic

Regulation number: 21 CFR 888.3060
Regulation name: Appliance Fixation, Spinal Intervertebral Body
Product Code: KWQ

Regulation number: 21 CFR 888.3040
Regulation name: Smooth or threaded metallic bone fixation fastener
Product Code: HWC

PREDICATE DEVICES

MacroPore *OS* Spinal System K010911
MacroPore Hydrosorb Spine System K041105

CONFORMANCE WITH PERFORMANCE STANDARDS

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

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

Inion S-1™ Biodegradable Anterior Cervical Fusion System, in conjunction with traditional rigid fixation (i.e., posterior interspinous wiring), is intended for use in cervical spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing indications.

Inion S-1 ™ Biodegradable Anterior Cervical Fusion System consist of cervical spinal fusion plates and screws, and is made of resorbable polylactic acid copolymers, P(L/DL)LA 80:20.

Based on in vitro testing: Inion S-1 Biodegradable Anterior Cervical Fusion System retain most of it's strength up to 16 weeks and gradually loose it's strength thereafter; and bioresorption takes place within two to four years.

Inion S-1 ™ Biodegradable Anterior Cervical Fusion System is provided sterile to the user and is non-pyrogenic. The shelf life of the device is 3 years.

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 S-1 ™ Biodegradable Anterior Cervical Fusion System are substantially equivalent with the predicate devices MacroPore *OS* Spinal System (K010911) and MacroPore Hydrosorb Spine System (K041105).

Inion S-1 ™ Biodegradable Anterior Cervical Fusion System is substantially equivalent to predicate Class II devices used in conjunction with traditional rigid fixation (i.e., posterior interspinous wiring) in cervical spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts, because the differences between Inion S-1 ™ Biodegradable Anterior Cervical Fusion 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 25 2008

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

Re: K051821
Trade/Device Name: Inion S-1™ Biodegradable Anterior Cervical Fusion System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: II
Product Code: OJB
Dated (Date on orig SE ltr): November 25, 2005
Received (Date on orig SE ltr): November 25, 2005

Dear Ms. Marttinen:

This letter corrects our substantially equivalent letter of November 25, 2005.

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 (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.

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.

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) 276-0120. 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 toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/dsma/dsmamain.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): K051821

Device Name: Inion S-1™ Biodegradable Anterior Cervical Fusion System

Indications for Use:

INDICATIONS

The **INION S-1™ BIODEGRADABLE ANTERIOR CERVICAL FUSION SYSTEM,** in conjunction with traditional rigid fixation (i.e., posterior interspinous wiring), is intended for use in cervical spinal fusion procedures as a means to maintain the relative position of weak bony tissue such as allografts and autografts. This device is not intended for load bearing indications.

CONTRAINDICATIONS

The **INION S-1™ BIODEGRADABLE ANTERIOR CERVICAL FUSION SYSTEM** implants are not intended for use in and are contraindicated for:

- Load bearing indications unless used in conjunction with traditional rigid fixation.
- Active or potential infection.
- Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse).

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

(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 K051821