DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 6, 2015

Inion Oy
% Ms. Kati Marttinen
Quality and Regulatory Director
Lääkärinkatu 2
Tampere, 33520
FINLAND

Re: K151360
Trade/Device Name: Inion Spinal Graft Containment System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: OJB
Dated: August 20, 2015
Received: September 2, 2015

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 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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/Contraindications 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 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

William H. Maisel -S

William H. Maisel, MD, MPH
Director (Acting)
Office of Device Evaluation
Deputy Center Director for Science
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K151360

Device Name

Inion Spinal Graft Containment System

Indications for Use *(Describe)*

The Inion spinal graft containment plate 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. This device is not intended for load bearing indications.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY
Inion Spinal Graft Containment System

Manufacturer and submitter:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date	August 20, 2015
Contact person	Kati Marttinen, Quality and Regulatory Director Phone: +358 10 830 6600 Fax: +358 10 830 6691 kati.marttinen@inion.com
Establishment registration number	9710629
Trade name of the device	Inion Spinal Graft Containment System
Device classification	Class II
Product code	OJB
Review panel	Orthopedic
Common name	Graft containment plate
Classification name	Spinal intervertebral body fixation orthosis
Regulation number	888.3060
Predicate device	Inion Spinal Graft Containment System (K071810)
Conformance with performance standards	Compliance to voluntary consensus standards is listed in the application.

Device description and principles of operation

INION S-2™ Biodegradable Anterior Thoraco-Lumbar Fusion System plates are bioresorbable anterior thoraco-lumbar fusion devices for graft containment (screws and plates). The plates are made of degradable poly(L-lactide-co-D,L-lactide 80:20). 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 implants are provided sterile to the user and are non-collagenous. The shelf life of the device is 3 years.

INION S-2™ Biodegradable Anterior Thoraco-Lumbar Fusion System devices provide fixation and are not intended to replace healthy tissues or withstand the stress of full load bearing.

The purpose of this submission is a line extension for new sizes.

510(k) SUMMARY
Inion Spinal Graft Containment System

Indications for use

The Inion Spinal Graft Containment plate 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. This device is not intended for load bearing indications.

Similarities to predicate device

In comparison to predicate device, the new plates have the same indications for use, material composition, manufacturing steps, sterilization method, packaging, shelf life and degradation profile. The new plates are inserted using the predicate device Inion S-2™ system screws unmodified, and same accessory instrumentation.

Differences to predicate device

In comparison to predicate device, the new plates have different dimensions. Width is 15 mm (predicate device 28 – 120 mm). Height range is 31-40 mm (predicate device 37 – 80 mm). Thickness is 3.2 mm which is within the range of predicate device (0.75 – 4.5 mm). The new plates have also less screw holes, one at each end, and are therefore fixed with 2 screws. The predicate device plates have 4-6 screw holes, 2-3 at each end respectively. The new plates do not contain radiographic tantalum markers, while majority of the predicate device plates contain 2 tantalum markers.

Accessory instruments

Surgical instruments include plate templates, plate holders, drill bits and bone taps, screwdrivers, temporary fixation screw, awl and alike. The instruments are made of surgical grade stainless steel or titanium. The instruments are provided nonsterile and reusable, intended to be steam sterilized by the user prior to use. Instructions for cleaning and steam sterilization are provided with the instruments.

Performance testing for substantial equivalence determination

Mechanical testing was conducted to verify the strength and fixation properties of the new Inion S-2™ plates and to compare them to the predicate device. Testing included Graft push-off test, torsion test, axial tensile test, axial compression test, and cyclic compressive bending test. The results of each mechanical test show that the new plates perform within the performance range of the predicate device.

Functional and handling test and simulated clinical use test were performed to verify that the new plates, fixed with predicate device unmodified screws, using accessory instruments, packaging and Instructions for Use are functioning together as intended, and conform to the defined user needs and intended uses.

510(k) SUMMARY
Inion Spinal Graft Containment System

The data demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of new Inion S-2™ line extension plates are substantially equivalent with the predicate device Inion Spinal Graft Containment System (K071810).