510(k) SUMMARY
Inion FreedomScrew™

FEB 2 7 2013

Manufacturer and submitter:	Inion Oy, Lääkärinkatu 2, FIN-33520 Tampere, FINLAND
Date of this summary:	November 23, 2012
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 FreedomScrew™
Device classification and product code	Class II Classification Panel: Orthopaedic Product Code: HWC Common name: Bone screw Regulation number: 888.3040
Predicate device	K031961 K043142 K030900
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 FreedomScrew™ implants are internal fracture fixation devices made of degradable co-polymer composed of 100 % poly(L-lactide-co-D,L-lactide). Based on *in-vitro* testing, the implants retain their initial strength up to 12 weeks after implantation, and gradually lose their strength thereafter. Bioresorption takes place within two to four years.

Inion FreedomScrews™ are in the range of diameter: 2.0 – 4.5 mm and length: 10 – 90 mm. The designs include fully and partially threaded screws, as well as solid and cannulated screws. Inion FreedomScrew™ implants are used together with the previously cleared Inion OTPS™ plating systems, as well as alone according to their indications for use. The Inion FreedomScrew™ products provide fixation and are not intended to replace healthy bone or withstand the stress of full load bearing.

Inion FreedomScrews™ are provided sterile to the user and are non-collagenous. The shelf life of the device is 3 years and they are intended for single use only.

The Inion FreedomScrews™ are primarily designed to be used with customized Inion instrumentation, such as drill bits, bone taps, holding sleeves, screwdriver shafts, countersinks, depth gauges, K-wires and cutting instruments, as well as with ISO 5835/ISO 9714 compatible instrumentation.

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Indications for use

The Inion FreedomScrew™ products are intended for maintenance of alignment and fixation of bone fractures, comminuted fractures, osteotomies, arthrodeses or bone grafts (i.e., autografts or allografts) in the presence of appropriate additional immobilization (e.g., rigid fixation implants, cast or brace).

In addition, the Inion FreedomScrew™ Ø3.5/4.0/4.5 mm products are specifically intended for use in following indications:

A. General indications: maintenance of reduction and fixation of cancellous bone fractures, osteotomies or arthrodeses of the upper extremity, ankle and foot in the presence of appropriate brace and/or immobilization.

B. Specific indications: fractures and osteotomies of the malleoli, and ankle fractures.

Performance testing for substantial equivalence determination

Mechanical shear, torsion and pull-out tests were performed to verify the strength properties of Inion FreedomScrew™ implants and to compare them to the predicate devices. Mechanical fixation test was performed to verify the properties of Inion FreedomScrew™ with the Inion FreedomPlate™ and to compare them to the fixation properties of the predicate devices. Fixation tests with Inion FreedomPlate™ included the technique of removing the screw heads after insertion by cutting forceps or heat loop device, where plate-screw interface creates appropriate grip and secures fixation.

In vitro degradation testing was carried out to determine the degradation profile (i.e., change in material and mechanical properties) and verify the sufficiency of the mechanical stability over healing period as the polymer degrades during in vitro degradation and to ensure the degradation of the Inion FreedomScrews™.

Functional and handling test and simulated clinical use test were performed to verify that the implants, accessory instruments, packaging and instructions for use are functioning together as intended, and conform to the defined user needs and intended uses. The tests were done also in comparison to the predicate devices.

The data demonstrates that the intended use, material composition and scientific technology, degradation profile and mechanical properties of Inion FreedomScrew™ are substantially equivalent with the predicate devices Inion OTPS™ Mesh System (K031961), Inion OTPS™ Mini Screws (K043142) and Inion OTPS™ Fixation System (K030900). The devices have passed the tests for functionality and handling in simulated clinical use settings and compare favourably to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

February 27, 2013

Inion Oy
% Ms. Kati Marttinen
Quality and Regulatory Director
Lääkärinkatu 2
335200 Tampere
Finland

Re: K123672
Trade/Device Name: Inion FreedomScrew™
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: November 23, 2012
Received: November 29, 2012

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. 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Statement of Indications for Use

510(k) Number: K123672 (pg 1/1)

Device Name: Inion FreedomScrew™

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B. Specific indications: fractures and osteotomies of the malleoli, and ankle fractures.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Divison of Orthopedic Devices