INION
Intelligent Solution

MAY 3 0 2003

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510(k) SUMMARY

Inion OTPS™ Biodegradable Mini Plating System

MANUFACTURER

Inion Ltd.
Lääkärinkatu 2
FIN-33520 Tampere

Contact Person:
Hanna Marttila
Regulatory Affairs Manager
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Hanna.Marttila@Inion.fi

DEVICE NAME

Trade name: Inion OTPS™ Biodegradable Mini Plating System
Common/Usual Name: Bone Plating System
Classification Name: Bone Plate, Screw

ESTABLISHMENT REGISTRATION NUMBER

9710629

DEVICE CLASSIFICATION AND PRODUCT CODE

Classification panel: Orthopedic
Regulatory Class: Class II
21 CFR 888.3040 – Smooth or threaded metallic bone fixation fastener, 87 HWC (screw)
21 CFR 888.3030 – Single multiple component metallic bone fixation appliances and accessories, 87 HRS (plate)

PREDICATE DEVICES

(1) Biomet Inc.; ReUnite Bone Screw (K992301)
(2) Biomet Inc.; LactoSorb Hand System (K991763)
(3) Syntehes(USA); Synthes Compact Hand 1.0/1.3 (pre-amendment device)

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Mini Plating System is intended for use in fixation of non-comminuted diaphyseal fractures of the metacarpal, proximal phalangeal, middle phalangeal and osteotomies in the presence of appropriate immobilization.

The Inion OTPS™ Biodegradable Mini Plating System is consisted of biodegradable screws and plates intended to be used in fractures of phalanges and metacarpal. Implants will be utilized by using common surgical techniques. The Inion OTPS™ Biodegradable Mini Plating System is made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. The Inion OTPS™ Biodegradable Mini Plating System implants gradually lose their strength during 18-36 weeks in vivo with complete strength loss and resorption within two to four years.

EQUIVALENCE TO MARKETED PRODUCTS

The Inion OTPS™ Biodegradable Mini Plating System is substantially equivalent to biodegradable implants, intended for metacarpal and phalangeal fracture fixation procedures, which have received 510(k) clearance. Inion OTPS™ Biodegradable Mini Plating System LactoSorb Hand System (K991763) and ReUnite Screw (K992301) have the same intended use and principles of operation and very similar design characteristics. Mechanical testing demonstrates that the device is substantially equivalent to the predicate ones. The differences between the Inion OTPS™ Biodegradable Mini Plating System and 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

MAY 3 0 2003

Ms. Hanna Marttila
Regulatory Affairs Manager
Inion Ltd.
Lääkärinkatu 2
Fin-33520 Tampere
Finland

Re: K023887
Trade/Device Name: Inion OTPS™ Biodegradable Mini Plating System
Regulation Number: 21 CFR 888.3040 and 888.3030
Regulation Name: Smooth or threaded metallic bone fixation fastener, and Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HWC and HRS
Dated: March 4, 2003
Received: March 6, 2003

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 (301) 594-4639. 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 may be obtained 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

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

D STATEMENT OF INDICATIONS FOR USE

Applicant: Inion Ltd.
510(k) Number: K023887
Device Name: Inion OTPS™ Biodegradable Mini Plating System

Indications:

The Inion OTPS™ Biodegradable Mini Plating System is intended for use in fixation of non-comminuted diaphyseal fractures of the metacarpal, proximal phalangeal, middle phalangeal and osteotomies in the presence of appropriate immobilization.

Contraindications:
Inion OTPS™ Biodegradable Mini Plating System is not intended for use in and is contraindicated for:
1. Active or potential infection
2. Patient conditions including limited blood supply, insufficient quantity or quality of bone; and where patient cooperation cannot be guaranteed. (e.g., alcoholism, drug abuse)
3. Load bearing procedures.

Prescription use Yes Over the Counter use No

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K023887

Date: 15.11.2002
Status: Final