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510(k) SUMMARY
for the Inion OTPS™ Biodegradable Mesh Plating System

MANUFACTURER
Inion Ltd.
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Contact Person:
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DEVICE NAME
Trade name: Inion OTPS™ Biodegradable Mesh Plating System
Classification Name: Bone, Plate

ESTABLISHMENT REGISTRATION NUMBER
9710629

DEVICE CLASSIFICATION AND PRODUCT CODE
Classification panel: Orthopedic
Regulatory Class: Class II
21 CFR 888.3030, 87 HRS (plate)

PREDICATE DEVICES

(1) MacroPore OS Trauma System (K021164)
(2) MacroPoreOS Protective Sheet (K994158)
(3) Synthes Resorbable Meshes and Sheets (K003788)

Date: 18.6.2003
Status: Final

DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION

The Inion OTPS™ Biodegradable Mesh Plating System is intended to maintain the relative position of weak bony tissue such as bone grafts, bone graft substitutes, or bone fragments from comminuted fractures.

The Inion OTPS™ Biodegradable Mesh Plating System is composed of various size mesh plates and associated fixations screws made of resorbable polylactic acid / trimethylenecarbonate copolymers [Poly (L-lactide-co-D,L-lactide) and poly (L-lactide-co-trimethylenecarbonate)]. The Inion OTPS™ Biodegradable Mesh 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™ Mesh Biodegradable Plating System is substantially equivalent to biodegradable implants, indicated for the reinforcing of weak bony tissues in orthopaedic procedures and when used in conjunction with traditional rigid fixation., which have received 510(k) clearance, including MacroPoreOS Trauma System (K021164), MacroPoreOS Protective Sheet (K994158) and Synthes Resorbable Meshes and Sheets (K003788). These devices 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. Differences between The Inion OTPS™ Biodegradable Mesh Plating System and predicate devices do not raise any new questions of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR - 1 2004

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

Re: K031961
Trade/Device Name: Inion OTPS™ Biodegradable Mesh Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: December 2, 2003
Received: December 4, 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,

Miriam C. Provost

for 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

Indications for Use

510(k) Number (if known): K03196/

Device Name: Inion OTPS™ Biodegradable Mesh plating System

Indications For Use:

The Inion OTPS™ Biodegradable Mesh Plating System is intended to sustain the relative position of weak bony tissue, e.g. bone grafts, bone graft substitutes, or bone fragments from comminuted fractures. The Inion OTPS™ Biodegradable Mesh Plating System is also indicated for cement restriction in total joint arthroplasty procedures.

Only when used in conjunction with traditional rigid fixation, the Inion OTPS™ Biodegradable Mesh Plating System is intended to sustain the relative position of weak bony tissue in trauma and reconstructive orthopaedic procedures involving the following:

- Long bones
- Flat bones
- Short bones
- Irregular bones
- Appendicular skeleton
- Thorax

When used alone (without traditional rigid fixation), the Inion OTPS™ Biodegradable Mesh Plating System is intended to maintain the relative position of bone grafts or bone graft substitutes in reconstructive orthopaedic procedures involving:

- Tumor resections where bone strength has not been compromised.
- Iliac crest harvest sites.

Prescription Use Yes AND/OR Over-The-Counter Use No
(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)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K03196/