

MAR 31 2004

K033074



**510(k) SUMMARY**

**Product: Inion GTR™ Biodegradable Membrane System**  
**Date: 09/19/2003**

**MANUFACTURER**

Inion Ltd.  
Lääkärintäti 2  
FIN-33520 Tampere

Contact Person:  
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Regulatory Affairs Coordinator  
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**DEVICE NAME**

Trade name: Inion GTR™ Biodegradable Membrane System  
Common/Usual Name: Biodegradable GTR™ Membrane and Tacks

**ESTABLISHMENT REGISTRATION NUMBER**

9710629

**DEVICE CLASSIFICATION AND PRODUCT CODE**

Classification panel: Dental  
Regulatory Class: Unclassified  
Bone Filling Augmentation Material has been assigned Product Code LYC.

GTR Membrane

Date: 19.9.2003  
Status: Final

## **PREDICATE DEVICES**

- (1) Atrix Laboratories, Inc.; Atrisorb®Bioabsorbable Guided Tissue Regeneration (GTR) Barrier (K955838)
- (2) W.L. Gore & Associates, Inc.; Gore Resolut™ XT Regenerative Material (973594) and Gore OsseoQuest Regenerative Membrane (K973594)
- (3) Geistlich- Pharma; Resor Pin Resorbable Membrane Pin (K972817)

## **INTENDED USE**

### **1.1 Indications for Use**

The Inion GTR™ Biodegradable Membrane System is indicated for the surgical treatment of periodontal defects to aid in the regeneration and integration of tissue components in guided tissue regeneration procedures (e.g. class II furcation defects, intrabony defects and recession type defects), for pre-implant and peri-implant surgery and for covering bone defects and empty sockets.

### **1.2 Contraindications**

The Inion GTR™ Biodegradable Membrane System should not be used in patients with active or potential infections, patient conditions including limited blood supply, when patient cooperation cannot be guaranteed (e.g., alcoholism, drug abuse), and in load bearing indications unless used in conjunction with traditional rigid fixation. There are currently no known additional contraindications to the use of the Inion GTR™ Biodegradable Membrane.

## **DEVICE DESCRIPTION AND PRINCIPLES OF OPERATION**

The Inion GTR™ Biodegradable Membrane System, intended to be used as a barrier membrane in GTR (guided tissue regeneration ) and GBR (guided bone regeneration), consists of membranes and separately available tacks made of degradable co-polymers composed of L-lactic, D-lactic, glycolic acid and trimethylene carbonate.

The membrane provides a barrier that is stable over 8-12 weeks in vivo. Bioresorption takes place within one to two years. NMP (N-methyl-2-pyrrolidone) plasticizer temporarily softens the membrane and is used to facilitate the handling and shaping of the membrane. Plasticizer is added into the membrane just before the operation.

The membranes are fastened in position by using separately available Inion GTR™ tacks or commercially available resorbable sutures. The Inion GTR™ Biodegradable System tack loses its strength over 12-26 weeks *in vitro* with complete strength loss and resorption within two to four years.

## **EQUIVALENCE TO MARKETED PRODUCTS**

The Inion GTR™ Biodegradable Membrane System is substantially equivalent to those of the previously accepted and clinically successfully used biodegradable GTR membranes and tacks intended for similar indications.

Inion GTR™ Biodegradable Membrane System Atrisorb® Bioabsorbable Guided Tissue Regeneration (GTR) Barrier (K955838), Gore Resolut™ XT Regenerative Material and OsscoQuest Regenerative Membrane (K973594) and Resor Pin Resorbable Membrane Pin (K972817) have the same principles of operation and very similar design characteristics. Extensively testing demonstrates that the device is substantially equivalent to the predicate ones. Differences between the Inion GTR™ Biodegradable Membrane System and predicate devices do not raise any new questions of safety and effectiveness.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville, Maryland 20850

OCT 10 2007

Ms. Hanna Marttila  
Regulatory Affairs  
Inion Limited  
Laakarinkatu 2  
FIN-33520 Tampere  
FINLAND

Re: K033074  
Trade Name: Inion GTR™ Biodegradable Membrane  
Regulation Number: 872.3930  
Regulation Name: Bone Grafting Material  
Regulatory Class: 2  
Product Code: NPK  
Dated: January 13, 2004  
Received: January 15, 2004

Dear Ms. Marttila:

This letter corrects our substantially equivalent letter of March 31, 2004.

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.

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) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Chiu Lin, Ph.D.

Director

Division of Anesthesiology, General Hospital,

Infection Control and Dental Devices

Office of Device Evaluation

Center for Devices and

Radiological Health



*Protecting and Promoting Public Health*

K033074

### Indications for Use

510(k) Number (if known): K033074

Device Name: Inion GTR™ Biodegradable Membrane

Indications For Use:

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Prescription Use    
 (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use    
 (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Susa Rinn

(Division Sign-Off)  
Division of Anesthesiology, General Hospital,  
Infection Control, Dental Devices

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