FEB 2 2006

K043178

510(K) SUMMARY

FOI RELEASABLE

Persuant to § 513(i)(3)(A) of the Food, Drug, and Cosmetic Act, grantAdler is required to submit with this Premarket Notification "...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." grantAdler chooses to submit a summary of information respecting safety and effectiveness.

Classification Name:	Port & Catheter, Implanted, Subcutaneous, Intravascular
Common/Usual Name:	Intravascular Access Port
Proprietary Name:	Rhapsody™ Port and Catheter
Device Classification:	Class II

Name	Number	21 CFR Ref.
Port & Catheter, Implanted, Subcutaneous, Intravascular	80 LJT	§ 880.5965

Owner/Operator: grantAdler Corporation
1994 Banbury Avenue
Yorkville, IL 60560
Phone: 630 302-4944

Contact Person: Michael Loiterman, President

Manufacturer: Medical Murray, Inc.
1294 Barclay Blvd.
Buffalo Grove, IL 60089
Phone: 847 419-0090

DESCRIPTION OF DEVICE

The grantAdler Implantable Access Ports are implantable ports for intraveneous injections.

INDICATIONS FOR USE

The grantAdler port line is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products, or the sampling of blood.

DESCRIPTIVE AND TECHNOLOGICAL CHARACTERISTICS OF PROPOSED AND PREDICATE DEVICES

The grantAdler Implantable Access Ports are supplied as sterile devices, and are intended for single patient use only. The ports are available as a single model and are manufactured of the highest quality titanium. They also incorporate a durable high compression self-sealing silicone septum. Catheter materials include flexible, non-compressible, and reinforced silicone. Suture sites are incorporated into the port base to facilitate anchorage to the underlying fascia.

The grantAdler Implantable Access Ports have the same descriptive and technological characteristics as the Horizon Medical Products, Inc. (HMP) Triumph-1 Ports K951814 and numerous other implantable access ports on the market today.

PERFORMANCE CHARACTERISTICS

Laboratory testing regarding characteristics was performed on the grantAdler Implantable Access Ports to verify its safety and performance. Biocompatibility assessments were performed on the materials in the grantAdler Implantable Access Ports with satisfactory results.

CONCLUSION

grantAdler believes that the grantAdler Implantable Access Port is substantially equivalent to the currently marketed Horizon Medical Products, Inc. (HMP) Triumph-1 Port K951814. A comparison of the descriptive characteristics of these products demonstrate the grantAdler Implantable Access Ports is equivalent in its indications for use, as well as in design and materials.

The information presented provides assurance that the grantAdler Implantable Access Ports will meet the minimum requirements that are considered acceptable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 2006

Mr. Michael Loiterman
President
grantAdler Corporation
1994 Banbury Avenue
Yorkville, Illinois 60560

Re: K043178
Trade/Device Name: grantAdler Rhapsody Access Port and Catheter
Regulation Number: 21 CFR 880.5965
Regulation Name: Subcutaneous, Implanted, Intravascular Infusion Port and Catheter
Regulatory Class: II
Product Code: LJT
Dated: January 19, 2006
Received: January 19, 2006

Dear Mr. Loiterman:

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.

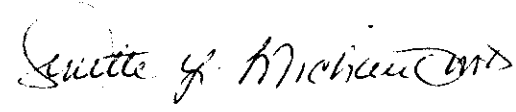
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0115. 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 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/industry/support/index.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

Enclosure

Indications for Use

510(k) Number (if known): K043178

Device Name: grantAdler Rhapsody Access Port and Catheter

Indications for Use: The grantAdler Rhapsody Access Port and Catheter is indicated for any patient requiring reliable repeated access of the vascular system for delivery of medications, nutritional supplementation, fluids, blood, blood products or the sampling of blood.

Prescription Use ✓ (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)

Division of General Hospital Devices

K043178