

K972555

December 22, 1997

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2a. & 2d. Summary of Safety and Effectiveness Information:

Company Name and Address: Gerard Medical, Inc.
6 City Depot Rd.
P.O. Box 940
Charlton City, MA 01508

Company Telephone No.: (508) 248-1562

Company Contact Name: Richard Cayer, Jr.

Summary Date: September 24, 1997

Proprietary Name: Catheter Tunneler

Common or Usual Name: Tunneler (accessory to catheter or implanted vascular access system)

Classification Name: Surgical Tunneler

Class: Unclassified

Legally Marketed Substantially Equivalent Device:

Catheter Tunneler. Manufactured by Bard Access Systems
(Division of C.R. Bard, Inc.)

Device Description and Intended Usage:

Gerard Medical plans to manufacture and market a catheter tunneler. This device will be used to create a subcutaneous path for an intraluminal catheter. The design of the device is such that the distal tip can separate subcutaneous tissues when manual force is applied in the direction of the tip along the length of the device proximal to the tip. The device has a means to connect the catheter in order to draw it through the subcutaneous tunnel. The tunneler may be constructed of any material (eg. metal or plastic) which permits separation of, and passage through, subcutaneous layers and is suitable for contact with this tissue. The initial device that we plan to produce and market is made of the plastic Delrin 500. We may, at a later date, provide an additional model that would consist of a medical grade stainless steel.

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2a. & 2d. Summary of Safety and Effectiveness Information
(continued):

When utilized during a surgical procedure, the tunneler must be able to withstand the force applied to create the subcutaneous path. Also, during this procedure, the catheter must remain connected to the distal end of the device.

As part of the Manufacturing Specification that we are creating for this device, we will mandate that the following tests be performed for the appropriate percentage of our finished devices prior to their being released for usage.

Test #1:

With the distal end (i.e. front end) of the device squarely abutted against an immovable flat surface, a 5 pounds force test will be performed.

Test #2:

With a catheter connected to the proximal end (i.e. back end) of the device, a 2 pound tension test will be performed. For this test the catheter will be pulled in two directions, both linearly (i.e. straight) and at a 45 degree angle.

Note that, based on our bench testing, the above levels of stress are significantly higher than would be anticipated during the actual surgical procedure.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Richard Cayer, Jr.
President
Gerald Medical, Incorporated
6 City Depot Road
P.O. Box 940
Charlton, Massachusetts 01508

DEC 22 1997

Re: K972555
Trade Name: Catheter Tunneler
Regulatory Class: Unclassified
Product Code: LJS
Dated: September 24, 1997
Received: September 29, 1997

Dear Mr. Cayer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

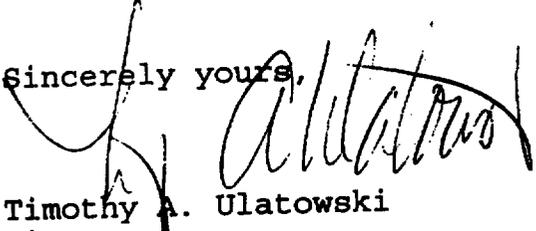
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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,


Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): 14972555

Device Name: Catheter Tunneler

Indications For Use:

A catheter tunneler is indicated whenever a surgeon would like to create a minimally invasive subcutaneous path for an implanted catheter. The implanting surgeon would oftentimes utilize the tunneler when implanting our TrimPort Systems. Our TrimPort Implantable Port Systems are indicated whenever patient therapy requires repeated intravascular injection or continuous infusion of fluids, medications, antibiotics, nutritionals and the withdrawal of venous blood samples.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number _____

Prescription Use X
Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

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