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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: November 29, 1997

Proprietary Name: TrimPort

Common or Usual Name: Implanted Vascular Access System

Classification Name: Implanted Subcutaneous IV Catheter

Class: [REDACTED]

Legally Marketed Substantially Equivalent Devices:

MiniPort Implantable Vascular Access System (Re: K942623).
Manufactured by Gerard Medical, Inc.

Device Description and Intended Usage:

The Gerard Medical, Inc. TrimPort Implantable Access System is precision engineered to provide repeated access to the vascular system for both parenteral delivery of fluids and the withdrawal of venous blood.

The implantable segments of the TrimPort System and comparable devices are the portal, the radiopaque catheter, and a locking catheter connector.

The small veins in one's arms and hands can become severely damaged when subjected to frequent needle punctures and/or irritating fluids. Usage of a TrimPort device, which is implanted beneath the skin, frees patients from the discomfort and potential damage to veins from repeated injections into them.

The TrimPort catheter is implanted into a large blood vessel so that fluids can be introduced or blood withdrawn without the necessity for repeated injections into the patient's vein.

Once the implanted TrimPort is ready for use, the physician or nurse will cleanse the skin at the implantation site and will pinpoint the device's location by simply feeling the unobtrusive but clear outline of its top rim. A needle specific to this purpose will be inserted gently through the skin into the portal of the TrimPort, where it will remain throughout the fluid delivery-withdrawal process.

Device Design, Testing, and Potential Adverse Occurrences:

We have reviewed a great quantity of information regarding our own and many competitive implantable vascular access systems. Based on our analysis, we feel that there are specific occurrences that would negatively affect the safety and effectiveness of these devices. The following is a list of these potential adverse occurrences and a summary of what we have done to minimize the risks.

1. Catheter Disconnection:

We designed an excellent catheter locking mechanism that remains intact, even under extreme conditions.

To ensure that the surgeon implanting our TrimPort assembles the locking device properly, we provide clear and complete instructions and diagrams in our "Instructions for Use".

2. System Leak:

We precisely engineered our TrimPort vascular access systems so that they perform properly (Re: two-way flow, leak tight), even under extreme misuse conditions. To ensure this, we mandate that all new designs must be able to pass each of our standard usage and extreme misuse tests.

To minimize the possibility of misuse, we instruct those who access the device to use syringes that are 10cc or larger. This helps to prevent the emission of damaging pressure into the system. Our recommendations to use 10cc or larger syringes and not to exceed 40 psi when using the system is stated several times in our "Instructions for Use". Note that this is also a standard warning in the competitive instruction manuals we have reviewed.

3. System Occlusions:

We make numerous references, and provide much direction, in our "Instructions for Use" relative to flushing our device and clearing system occlusions.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 7 1998

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

Re: K974533
Trade Name: TrimPort® Implantable Access System
Regulatory Class: Unclassified
Product Code: LJT
Dated: April 23, 1998
Received: April 27, 1998

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the TrimPort® Implantable Access System have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket 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

Page 2 - Mr. Cayer

the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, FDA will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, the Food and Drug Administration (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 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 the labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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/dsma/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

510(k) Number (if known): K974533

Device Name: TrimPort Implantable Access System

Indications For Use:

Our TrimPort Systems are indicated for use 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)

Palmina Curcetti

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

510(k) Number K974533

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use