

AUG - 7 1998

510(k) Summary  
Genzyme Surgical Products  
Millennium Valve Introducer/Rotator Handle  
(per 21 CFR 807.92)

1. SUBMITTER NAME AND ADDRESS

Genzyme Surgical Products  
5175 South Royal Atlanta Drive  
Tucker, GA 30084

Contact Person: Michelle M. Johnston  
Telephone: 770-496-0952

Date Prepared: March 23, 1998

2. DEVICE NAME

Proprietary Name: Millennium Valve Introducer/Rotator Handle  
Common/Usual Name: Introducer/Rotator Handle  
Classification Name: Accessory to Valve Holder or Valve

3. PREDICATE DEVICE

Diamond Touch and Micro Diamond Touch/Diamond Line Instruments K960400

Carbomedics Extended Mitral Rotator K951368

Carbomedics Handle K962154

4. DEVICE DESCRIPTION

The Millennium Valve Introducer/Rotator Handle (Introducer/Rotator Handle) consists of a handle, flexible shaft, and tip. The Handle includes two knobs that control the orientation and position of the tip. The proximal knob tightens the cable that adjusts the tip between 0 and 90 degrees. The distal knob rotates the tip between 0 and 360 degrees.

**5. INDICATIONS FOR USE**

The Genzyme Surgical Products Millennium Valve Introducer/Rotator Handle is indicated for use during open and minimally invasive cardiac valve surgeries. This instrument is indicated for surgical introduction and rotation of a Sulzer Carbomedics Low Profile Mitral Valve Sizer and Rotator.

**6. BASIS FOR SUBSTANTIAL EQUIVALENCE**

Operational and technological characteristics form the basis for the determination of substantial equivalence of the proposed Introducer/Rotator Handle and the predicate devices. Information provided in this 510(k) premarket notification includes descriptive information about the intended use, operation, and technological characteristics. A side-by-side comparison of the two instrument systems is provided in the table below.

Comparison of the Millennium Valve Introducer/Rotator Handle and Predicate Devices

Characteristic	Millennium Valve Introducer/Rotator Handle (proposed)	Diamond Touch and Micro Diamond Touch (K960400)	Carbomedics Extended Mitral Rotator (K951368) Carbomedics Handle (K962154)
Indicated for minimally invasive cardiovascular surgery	Yes	Yes	Unknown
Indicated for valve repair/replacement	Yes	No	Yes
Indicated for valve repair/replacement	Yes	No	Yes
Materials: ASTM Surgical Stain steel and Aluminum	Yes	Yes	Unknown
Sterility Status: Reusable	Yes	Yes	Yes
Sterilization Process	Steam	Steam	Steam



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Genzyme Surgical Products  
c/o Ms. Rosina Robinson  
Senior Staff Consultant  
Medical Device Consultants, Inc.  
49 Plain Street  
North Attleboro, MA 02760

Re: K980016  
Millennium Valve Introducer/Rotator Handle  
Regulatory Class: unclassified  
Product Code: MOP  
Dated: March 24, 1998  
Received: March 25, 1998

Dear Ms. Robinson:

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. 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 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, 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 pre-market 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.

Page 2 - Ms. Rosina Robinson

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), promotion, or advertising, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/dsma/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory,  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K980016

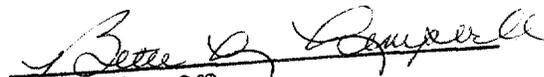
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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number K980016

Prescription Use X  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)