

K 965137

JUN - 4 1997

510(k) Summary

A. Determination of Substantial Equivalence

The Fogarty® Valvulotome is substantially equivalent to the Intramed® Valvulotome, which was cleared for marketing under premarket notification K925283.

B. Device Name

Fogarty® Valvulotome, Model 700091

C. Predicate Device

The claim of substantial equivalence is based on the following device:

- Intramed® Valvulotome, 510(k) No. K925283

D. Device Description

The modified Fogarty® Valvulotome, like the predicate device, consists of a flexible shaft with a cutting blade at the distal tip and a handle at the proximal end. The mode of operation for both devices is the same. The device is inserted into the vessel in an antegrade direction until the blade is located above the cusp of a venous valve. The location of the valve is visualized via an angioscope or is directly visualized through the vein wall in an open procedure. The blade is withdrawn retrograde through the cusp, thereby rendering it incompetent. After the blade disrupts one cusp, it is then rotated 180° to disrupt the adjoining cusp segment.

The Fogarty® Valvulotome, like the predicate device, contains an irrigation lumen that provides irrigation/fluid flow during the valvulotomy procedure.

The predicate valvulotome was available in two sizes, 3.8 mm or 4.6 mm, with a shaft length of 90 cm. The modified device is available in one size that accommodates various vessel sizes and a usable length of 81 cm.

A modification to the Fogarty® Valvulotome was implemented that enhanced the strength of the attachment of the blade holder to the stop.

Other modifications to the device that have occurred since FDA clearance of the original valvulotome (Intramed® Valvulotome, K925283) are also included in this submission and include:

- The blade on the modified Fogarty® Valvulotome is retractable whereas the blade on the predicate device was not. The size and shape of the blade have been changed to accommodate retractability.

- The material used for the shaft and handle have been changed; the modified materials have been determined to be biocompatible.
- The handle now includes a control button for extension and retraction of the blade and guidewire.

E. Intended Use of Device

The Fogarty® Valvulotome, like the predicate device, is intended to be used in the disruption of venous valves.

F. Intended Use of Predicate Device

The Intramed® Valvulotome is intended to be used in the disruption of venous valves.

G. Technological Comparison of the Fogarty® Valvulotome and the Predicate Device

The modified Fogarty® Valvulotome, like the predicate device, consists of a flexible shaft with a stainless steel cutting blade at the distal tip and a handle at the proximal end. Both contain an irrigation lumen that provides irrigation/fluid flow during the valvulotomy procedure. The mode of operation for both devices is the same as is the intended use. Therefore, the technological characteristics of Fogarty® Valvulotome are equivalent to those of the Intramed® Valvulotome.

H. Discussion of Non-Clinical Tests, Clinical Evaluations and Conclusions

The following non-clinical testing was performed on the Fogarty® Valvulotome:

- biocompatibility testing and
- functional/bench testing.

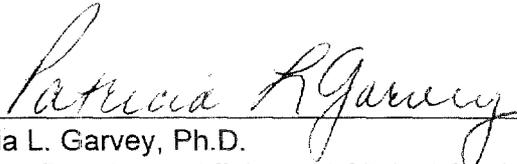
Biocompatibility testing was performed on valvulotome samples in accordance with the requirements specified in International Standards Organization (ISO) 10993-1-1994 Biological Evaluation of Medical Devices - Part 1: Guidance on Selection of Tests and the FDA General Program Memorandum No. G95-1. The valvulotome was found to be biocompatible and nontoxic and acceptable for its intended use.

Functional testing was performed on the Fogarty® Valvulotome to evaluate the integrity and performance of the device. The testing demonstrated that the product meets its performance requirements for its intended use.

In addition, Baxter conducted a clinical evaluation of the Fogarty® Valvulotome which demonstrated that the product is capable of disrupting venous valves during *in situ* saphenous vein grafting procedures.

I. Summary of Safety and Effectiveness

The above testing demonstrates that the Fogarty® Valvulotome is safe and effective for its intended use.



Patricia L. Garvey, Ph.D.
Director, Regulatory Affairs and Clinical Studies
CardioVascular Group



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 1997

Ms. Paula A. Torrianni
Senior Clinical Affairs Specialist
Baxter Healthcare Corporation
17221 Red Hill Avenue
P.O. Box 11150
Santa Ana, California 92711-1150

Re: K965137
Baxter Fogarty® Valvulotome
Regulatory Class: II (two)
Product Code: MGZ
Dated: April 4, 1997
Received: April 7, 1997

Dear Ms. Torrianni:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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 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) 594-4648. 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 at (301) 443-6597.

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): K965137

Device Name: Baxter Fogarty® Valvulotome

Indications For Use:

Food and Drug Administration
510(k) Notification for the Fogarty® Valvulotome

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Indications for Use

Reference: 510(k) Notification for the Baxter Fogarty® Valvulotome

The Fogarty® Valvulotome is indicated for use in veins during *in situ* or autologous bypass graft procedures.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Bette G. Comperle
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K965137

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)