

C.    510(k) Summary

Summary of safety and effectiveness for the Medi-Dyne Powerback Coronary Guiding Catheter

AUG - 1 1997

Submitter:            Medi-Dyne, Inc.  
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Queensbury, New York 12804  
Phone:            518-792-2183  
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Contact:             Norman L. Hall  
Manager, QA/Reg. Affairs

Date Prepared: January 30, 1997

<u>Device Name:</u>	Trade Name	-	Medi-Dyne Powerback Coronary Guiding Catheter
	Common Name	-	Coronary Guiding Catheter
	Classification	-	Percutaneous Catheter (per 870.1250)

SE to Marketed Device:

The Medi-Dyne Powerback Coronary Guiding Catheter is comparable to the Cordis Corporation Coronary Guiding Catheter (Petite Brite Tip™ and Vista Brite Tip™ models) and to the SCIMED Life Systems, Inc. Coronary Guiding Catheter (Triguide™ - Elite model).

Description and Intended Use:

The Medi-Dyne, Inc. Coronary Guiding Catheter is a single-use, sterile, nonpyrogenic, disposable cardiovascular catheter with a large nontapered lumen that permits the injection of contrast medium, pressure monitoring, and the passage of interventional devices such as balloon dilation catheters, guide wires and stents.

Technological Characteristics Comparison:

The Medi-Dyne device is similar in construction and materials when compared to the predicate devices. For example, both the Medi-Dyne and predicate device is manufactured with a plastic luer, radiopacifier loaded plastic shaft (jacket), a radiopacifier loaded soft tip, a teflon lined lumen, and an encapsulated layer of stainless steel braid between the inner teflon/liner and the outer plastic jacket. In addition, the lumens are similar in size, the distal ends are nontapered and sideholes are available.

Section 1            General Information

C.    510(k) Summary {Continued}

Assessment of Performance Data (Bench Tests):

The following nonclinical tests were performed:

1.    Tensile strength of catheter body
2.    Tensile strength of catheter body to luer attachment
3.    Catheter stiffness
4.    Catheter tip (distal) attachment strength
5.    Catheter elongation
6.    Leakage at hub
7.    Catheter burst test (positive internal pressure)
8.    Catheter collapse (negative internal pressure)
9.    Catheter flexural fatigue tolerance
10.   Curve retention
11.   Frequency response

Based on the above bench testing, it was determined that the Medi-Dyne catheter is safe and effective and is substantially equivalent to predicate devices noted above. The Medi-Dyne catheter equaled or exceeded values obtained on competitive products (1 thru 11). Review of competitive literature suggested no differences in indicated use or performance claims.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20856

AUG 1 1997

Mr. Norman Hall  
Medi-Dyne, Inc.  
604 Queensbury Avenue  
Queensbury, New York 12804

Re: K970401  
Coronary Guiding Catheter  
Regulatory Class: II (two)  
Product Code: 74 DQY  
Dated: May 27, 1997  
Received: May 29, 1997

Dear Mr. Hall:

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 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.

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) 594-4639. 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,

Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular,  
Respiratory, and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

D. Statement of Indications for Use

The Medi-Dyne, Inc. Coronary Guiding Catheter is designed to be used for the intravascular introduction of medical instruments into the coronary vascular system.

*Tam A. Ruv*

(Division Sign-Off)

Division of Cardiovascular, Respiratory,  
and Neurological Devices

510(k) Number

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