This summary of 510(k)-safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.
Date Prepared: 2/1/05

510(k) number: K042553

Applicant Information:

BioCardia, Inc.
384 Oyster Point Blvd. #5
South San Francisco, CA 94080

Contact Person:	Daniel C. Rosenman
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Device Information:

Classification:	Class II
Trade Name:	BioCardia Morph Universal Deflectable Guide Catheter
Classification Name:	Percutaneous Catheter (21 CFR 870.1250)

Equivalent Device:
The subject device is substantially equivalent in intended use and/or method of operation to the BioCardia Universal Deflectable Guide Catheter (K012749), SCIMED Triguide Guide Catheter (K961280), the USCI Mainstay Guiding Catheter (K971034) and the Cardima Naviport Deflectable Tip Guiding Catheter (K974683).

Intended Use:
The BioCardia Morph Universal Deflectable Guide Catheter is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices may be introduced into the peripheral vasculature or chambers and coronary vasculature of the heart.

Test Results:
Performance
Results of in-vitro and animal testing demonstrate that the BioCardia Morph Universal Deflectable Guide Catheter is safe and effective for its intended use.

Biocompatibility
The materials used in the BioCardia Morph Universal Deflectable Guide Catheter are identical to those used in other diagnostic catheters and meet the requirements of ISO 10993-1.

Summary: Based on the intended use, product, performance and biocompatibility information provided in this notification, the subject device has been shown to be substantially equivalent to the currently marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 17 2005

Mr. Daniel C. Rosenman
Vice President, Research and Development
BioCardia, Inc.
384 Oyster Point Blvd, #5
South San Francisco, CA 94080

Re: K042553
Trade/Device Name: BioCardia Morph Universal Deflectable Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: February 1, 2005
Received: February 2, 2005

Dear Mr. Rosenman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Vachner

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K042553

Device Name: BioCardia Morph Universal Deflectable Guide Catheter

Indications For Use: The BioCardia Morph Universal Deflectable Guide Catheter is intended to provide a pathway through which medical instruments, such as balloon dilatation catheters, guidewires, or other therapeutic devices may be introduced into the peripheral vasculature or chambers and coronary vasculature of the heart.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(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 Cardiovascular Devices

510(k) Number K042553