K971602 OCT 17 1997

510(k) Summary of Safety and Effectiveness
FloWire® 300 and FloWire® XT 300 Doppler Guide Wires

This 510(k) safety and effectiveness summary is being submitted in accordance with the requirements of Safe Medical Devices Act 1990 and 21 CFR §807.92.

General Information

Manufacturer:	Cardiometrics, Inc. 645 Clyde Avenue Mountain View, California 94043 (415) 961-6993
Contact Person:	Claire Andrews Vice President, Regulatory, Quality and Clinical Affairs
Date Prepared:	July 22, 1997

Device Information

Classification:	Class II
Trade Name:	FloWire® 300 Doppler Guide Wire FloWire® XT 300 Doppler Guide Wire
Common Name:	Catheter Guide Wire
Classification Name:	Catheter guide wire (§870.1330) Cardiovascular blood flow meter (§870.2100) Catheter tip pressure transducer (§870.2870) Vessel occlusion transducer (§870.2890) Patient transducer and electrical cable (§870.2900)
Predicate Device(s):	FloWire Doppler Guide Wire FloWire XT Doppler Guide Wire

Intended Use

The Cardiometrics FloWire 300 Doppler Guide Wire and the Cardiometrics FloWire XT 300 Doppler Guide Wires are intended for use in all blood vessels, including both coronary and peripheral arteries, to measure blood flow velocities during diagnostic angiography and/or interventional procedures. The FloWire may be used to guide the positioning of a balloon dilatation catheter, as well as other interventional devices. Blood flow velocity measurements are obtained to provide hemodynamic information for the diagnosis and treatment of coronary or peripheral artery disease.

Product Description

The FloWire 300/ FloWire XT 300 Doppler Guide Wire is a steerable guide wire with a ultrasound transducer mounted in a housing at the tip of the radiopaque tip coil. The FloWire 300/ FloWire XT 300 utilizes a coaxial design, has a nominal outer diameter of .014" throughout the entire length of the guide wire, and is approximately 300 cm in length. The FloWire 300/ FloWire XT 300 is constructed from a core wire, tapered at the distal end. Two different taper configurations are available, one is for the standard FloWire 300 Doppler Guide Wire, while the second configuration is for the FloWire XT 300 Doppler Guide Wire. The FloWire XT 300 Doppler Guide Wire has increased column strength in the distal segment of the wire just proximal to the tip of the wire, while retaining the floppy characteristics of the tip itself; the increased column strength provides additional support for tracking interventional devices, such as atherectomy devices, lasers and stents.

External to the core wire is a hypotube, proximal and tip coils, and the transducer housing. The hypotube extends from the conductive bands at the proximal end of the FloWire 300/FloWire XT 300 Doppler Guide Wire to the proximal coil. The distal tip is available in three different stiffnesses: floppy or flex. In addition, the FloWire 300/FloWire XT 300 Doppler Guide Wire is coated to provide lubricity for tracking interventional devices, such as balloon dilatation catheters. The FloWire 300/FloWire XT 300 Doppler Guide Wire connects to the FloMap/FloMap II Instrument via the Rotary Connector Cable and Patient Cable.

Substantial Equivalence

This 510(k) premarket notification is being submitted for a modification to the FloWire/FloWire XT Doppler Guide Wire. The guide wire length is being modified from 175 cm to 300 cm. The FloWire 300 Doppler Guide Wire and the FloWire XT 300 Doppler Guide Wire are substantially equivalent to the currently marketed Cardiometrics FloWire Doppler Guide Wire with CINCH® extension and the FloWire XT Doppler Guide Wire with CINCH® extension, respectively, with regard to intended use, function, materials, performance and sterilization method.

Biocompatibility Evaluations

The materials used in the FloWire 300/FloWire XT 300 Doppler Guide Wire have been tested for biocompatibility and meet the requirements for "Externally Communicating Devices, Circulating Blood, Limited Contact" as described in the FDA BlueBook Memorandum #G95-1 entitled, "Use of International Standard ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing". These biocompatibility test results support the safety of the device.

Functional and Mechanical Testing

Bench testing of the FloWire 300/FloWire XT 300 Doppler Guide Wire was conducted according to the FDA guidance document entitled, "Coronary and Cerebrovascular Guide Wire Guidance", dated January 1995. Evaluations completed were:

Turns-to-Failure
Torque Response

The joint tensile strength tests, along with coating/particulate testing and radiopacity evaluations were not performed again due to the FloWire 300/FloWire XT 300 Doppler Guide Wires being manufactured using the same materials with identical dimensions following the same procedures and processes as the FloWire/FloWire XT Doppler Guide Wire. The results from the tests performed on the FloWire/FloWire XT Doppler Guide Wire apply equally to the FloWire 300/FloWire XT 300 Doppler Guide Wire.

In addition to mechanical testing, acoustic performance testing was also performed to assure the performance of the FloWire 300/FloWire XT 300 Doppler Guide Wire was equivalent to the performance of the FloWire/FloWire XT Doppler Guide Wire.

Summary

Based upon the modifications described in this submission, the test data supports the substantial equivalence of the FloWire 300/FloWire XT 300 Doppler Guide Wire to the FloWire/FloWire XT Doppler Guide Wire.

Claire Andrews
Vice President, Regulatory, Quality and Clinical Affairs
Cardiometrics, Inc.
July 22, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

OCT 14 1997

Mr. Claire Andrews
Cardiometrics, Inc.
645 Clyde Avenue
Mountain View, California 94043

Re: K972762
Cardiometrics FloWire® 300 and FloWire® XT 300 Doppler Guide Wire
Regulatory Class: II (two)
Product Code: 74 DQX
Dated: July 22, 1997
Received: July 24, 1997

Dear Mr. Andrews:

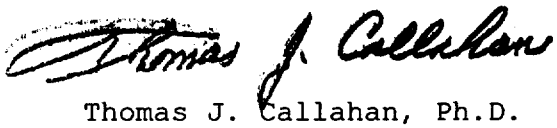
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 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 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) 594-4639. 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

510(k) Number (if known):_____

Device Name: Cardiometrics FloWire 300/FloWire XT 300 Doppler GuideWire

Indications For Use: The Cardiometrics FloWire 300 Doppler Guide Wire and the Cardiometrics FloWire XT 300 Doppler Guide Wires are intended for use in all blood vessels, including both coronary and peripheral arteries, to measure blood flow velocities during diagnostic angiograph and/or interventional procedures. The FloWire may be used to guide the positioning of a balloo dilatation catheter, as well as other interventional devices. Blood flow velocity measurements are obtained to provide hemodynamic information for the diagnosis and treatment of coronary or peripheral artery disease.

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(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K972762

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)