

K965140

510(k) Premarket Notification Submission
Cardiometrics WaveWire/WaveMap Pressure System

AUG 18 1997

SECTION 2.0
SUMMARY OF SAFETY AND EFFECTIVENESS

510(k) Summary of Safety and Effectiveness WaveWire™/WaveMap™ Pressure System

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: May 31, 1997

Device Information

Classification: Class II

Trade Names: WaveWire/WaveMap Pressure System
WaveWire Pressure Wire
WaveWire XT Pressure Wire
WaveMap Pressure Instrument

Common/Classification Names:
Guide, Wire, Catheter (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 Devices: FloWire®/FloMap® Doppler Ultrasound Instrument
AccuTrac™ Intravascular Guide Wire
Medtronic Floscan® Doppler Diagnostic Catheter
Millar Mikro-Tip® Catheter Pressure Transducer

Intended Use

The Cardiometrics WaveWire/WaveMap Pressure System is intended for use in the coronary and peripheral arteries to measure blood pressure during diagnostic and/or interventional procedures. The WaveWire may be used to guide the positioning of balloon dilatation catheters, as well as other interventional devices such as atherectomy devices, lasers and stents. Blood pressure measurements are obtained to provide hemodynamic information for the diagnosis and treatment of coronary and/or peripheral artery disease.

Product Description

The Cardiometrics WaveWire Pressure Wire is a steerable guide wire designed to perform real-time invasive pressure measurements in the vasculature. The WaveWire has a nominal outer diameter of either .014" or .018" and is 175 cm in length. It has a 3 cm shapeable radiopaque tip coil that is available in three different stiffnesses: floppy, flex and firm. The WaveWire XT Pressure Wire design provides increased column strength in the distal segment of the wire just proximal to the tip of the guide wire while retaining the floppy characteristics of the tip itself; the increased column strength supports certain interventional devices (Note: All other characteristics of the WaveWire XT Pressure Wire are the same as the non-XT WaveWire). A miniature pressure transducer is mounted at the junction of the radiopaque tip coil and the radiolucent proximal coil. The WaveWire Pressure Wire is connected to the WaveMap Pressure Instrument via a rotary connector cable and patient cable. Each rotary connector cable includes an identification memory chip containing the calibration constants for the pressure transducer. In addition, the WaveWire Pressure Guide Wire is designed to be compatible with the Cordis CINCH® extension system.

The WaveMap Pressure Instrument is intended for use only with the WaveWire Pressure Wire. The WaveMap is a microcomputer controlled instrument which processes the information from the transducer mounted in the WaveWire to produce real-time blood pressure measurements. The WaveMap provides digital readouts of mean aortic pressure from a guide catheter, mean WaveWire pressure, and a calculated parameter, such as gradient or fractional flow reserve (FFR). The WaveMap also supplies an analog output of the WaveWire pressure for display on a conventional physiologic monitoring system or strip chart recorder.

Substantial Equivalence

The WaveWire/WaveMap Pressure System is substantially equivalent in design to two currently marketed Cardiometrics products, the FloWire®/FloMap® Doppler Ultrasound Instrument, accession numbers K905411, K912776, K921563, K932536, K941485, K943022, and K955551 and the AccuTrac™ Intravascular Guide Wire, accession numbers K952562 and K961777. In addition, the WaveWire/WaveMap Pressure System's intended use, to measure and monitor intravascular blood pressure, is substantially equivalent to the Medtronic Floscan® Doppler Diagnostic Catheter, accession number K862673, and the Millar Mikro-Tip® Catheter Pressure Transducer, accession number K823434.

Biocompatibility Evaluations

The materials used in the WaveWire Pressure Wire are the same as those used in the FloWire Doppler Guide Wire and the AccuTrac Intravascular Guide Wire with the exception of two materials. The materials used in the FloWire and AccuTrac, along with the new materials, 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".

Bench Testing

Bench testing for the WaveWire Pressure Wire was conducted according to the FDA guidance document entitled, "Coronary and Cerebrovascular Guide Wire Guidance", dated January 1995. Evaluations completed were:

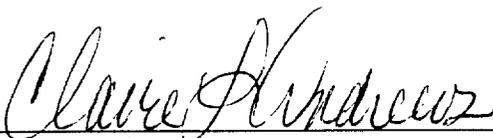
Screw Tip to Core Wire Joint Test
Screw Tip to Tip Coil Tensile Strength
Tip Coil to (Housing) Proximal Coil Tensile Strength
Proximal Coil to Hypotube Tensile Strength
Turns-to-Failure
Torque Response
Functional (Accuracy) Testing

Inadvertent disengagement (for the Cordis CINCH® Extension System), Coating and Particulate Testing, Radiopacity, Dome Integrity, Core Wire-to-Hypotube Joint Test, and Bending/Stiffness evaluations were not performed due to the similarity in design between the WaveWire Pressure Wire, the FloWire Doppler Guide Wire and AccuTrac Intravascular Guide Wire. The results from these tests equally apply to the WaveWire Pressure Wire.

Electrical safety testing was conducted to assure the WaveMap Pressure Instrument complies with the requirements of IEC-601-1, UL2601, CSA 22.2 and CSA601-1, Safety of Medical Electrical Equipment. Electromagnetic compatibility testing was conducted to assure the WaveMap Pressure Instrument complies with the requirements of IEC 601-1-2.

Summary

Based upon the information described in this submission, the functional/mechanical evaluations, biocompatibility testing, electrical safety testing, and electromagnetic compatibility testing the Cardiometrics WaveWire/WaveMap Pressure System has been shown to be substantially equivalent to the FloWire/FloMap Doppler Ultrasound Instrument, the AccuTrac Intravascular Guide Wire, the Medtronic FloScan Doppler Diagnostic Catheter and the Millar Mikro-Tip Catheter Pressure Transducer.



Claire Andrews
Vice President, Regulatory, Quality and Clinical Affairs
Cardiometrics, Inc.
May 31, 1997



AUG 18 1997

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Ms. Claire L. Andrews
Vice President, Regulatory,
Quality and Clinical Affairs
Cardiometrics, Inc.
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AUG 18 1997

Re: K965140
Cardiometrics WaveWire™/WaveMap™ Pressure System
Regulatory Class: II (two)
Product Code: DQX
Dated: June 9, 1997
Received: June 9, 1997

Dear Ms. 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 (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

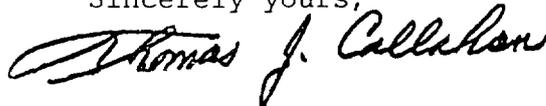
regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic 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

