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1.8 - Summary of Safety and Effectiveness

Premarket Notification K050088

1.8.1 Applicant

Cardiosonix, Ltd.
A Neoprobe Company
425 Metro Place North, Suite 300
Dublin, Ohio 43017-1367 U.S.A.
Telephone: +1 614-793-7500
Facsimile: +1 614-793-7520

1.8.2 Official Correspondent

Name:	Rodger A. Brown
Address:	425 Metro Place North Suite 300 Dublin, Ohio 43017-1367 U.S.A
Telephone:	+1 614-822-8342
Facsimile:	+1 614-822-8343
E-mail:	rbrown@neoprobe.com

1.8.2 Device Identification

Device Name:	Quantix/OR™ Blood Flow Monitor
Device Trade or proprietary Name:	Quantix/OR™ Flexible Probe; Quantix/OR™ Vessel Stabilizer
Common Name:	Blood Flowmeter
Classification Name:	Cardiovascular Blood Flowmeter, Class II, 870.2100

1.8.3 Predicate Device

The Quantix/OR™ Blood Flow Monitor with Flexible Probe and vessel Stabilizer is substantially equivalent to the following device(s):

Device	**Manufacturer**	**510(k) No.**
FlowGuard probe	Biosonix, Ltd.	K018303
Quantix/OR™ Blood Flow Monitor (Rigid probe)	Cardiosonix, Ltd.	K030357
Quantix/OR™ Vessel Stabilizer (Flexible probe)	Cardiosonix, Ltd.	K041180
Butterfly Flowmeter BF1000 – BF2004	Medi-Stim	K992305
Flowmeter	Transonic	K872048

1.8.4 Intended Use

The Quantix/OR™ Flexible Probe and optional Vessel Stabilizers are intended for invasive and noninvasive diagnostic blood flow measurements.

1.8.5 Description of the Device

The Quantix/OR™ Blood Flow Monitor with Flexible Probe and Vessel Stabilizer is a dual-beam, angle independent, pulse-wave Doppler ultrasound system for the invasive and noninvasive blood vessel flow measurements. In addition to the conventional Doppler (blood flow velocity) measurements, the Quantix/OR™ Flexible Probe technology utilizes ultrasound Doppler methods to obtain real-time measurements according to the definition of blood flow volume to target blood vessels. By definition, blood flow is the product of velocity cross-sectional area. In other words, the volume blood flow is calculated by deriving flow velocity from the Doppler shift frequency using the basic standard formula and then multiplying the velocity by the cross-sectional area of the blood vessel.

1.8.6 Technological Characteristics

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Flexible Probe and Vessel Stabilizer modifications are substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Neoprobe Corporation
c/o Mr. Rodger A. Brown
Vice President, Regulatory Affairs and Quality Assurance
425 Metro Place North, Suite 300
Dubin, OH 43017-1367

Re: K050088
Quantix/OR™ Blood Flow Monitor, Flexible Probe with optional Vessel Stabilizer
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: DPW
Dated: January 10, 2005
Received: January 13, 2005

Dear Mr. Brown:

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 (301) 594-4646. 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" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Donna R. Bachner

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

Enclosure

1.1 - Indications for Use Statement

510(k) Number (if known): K050088

Device Name: Quantix/OR™ Blood Flow Monitor

Indications for use:

The Quantix/OR Blood Flow Monitor is intended for invasive and noninvasive diagnostic blood flow measurements.

Prescription Use ☒ OR Over-The-Counter Use ☐
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(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 K050088