SECTION 6 - SUMMARY OF SAFETY AND EFFECTIVENESS

JUN - 7 2004

K041180
(Premarket Notification [510(k)] Number)

1. Applicant

Cardiosonix Ltd.
Beit Milenium
3 Hatidhar Str.
Rananna, 43654 ISRAEL
Tel: +972-9-7766444
Fax: +972-9-7766445

Corresponding Official:

Name: Ahava M. Stein, Consultant
Address: A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534

2. Device Name: Vessel Stabilizer

Device trade/proprietary name: Quantix OR + Vessel Stabilizer Device

Common Name: Blood Flowmeter

Classification Name: Cardiovascular Blood Flowmeter, Class II, 870.2100

3. Predicate Devices

The Quantix OR + Vessel Stabilizer device is substantially equivalent to the following device:

Device	Manufacturer	510(k) No.
Quantix OR device	Cardiosonix Ltd.	K030357

4. Intended Use

The Quantix OR + Vessel Stabilizer device is intended for intraoperative examinations of blood flow measurements.

5. Description of the Device

The Quantix OR + Vessel Stabilizer accessory is a dual-beam, angle-independent, pulse-wave Doppler ultrasound system used for intraoperative blood flow volume. In addition to the conventional Doppler (blood flow velocity) measurements, the Quantix OR + Vessel Stabilizer technology utilizes special applications of 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 and 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-section area of the blood vessel.

6. Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the Quantix OR + Vessel Stabilizer device are substantially equivalent to the predicate device cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 7 2004

Cardiosonix Ltd.
c/o Ms. Ahava Stein
Regulatory Affairs Consultant
Beit Hapa'amon (Box 124)
20 Hata'as Street, 44425
Kfar Saba ISRAEL

Re: K041180
Quantix OR with Vessel Stabilizer
Regulation Number: 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II (two)
Product Code: 74 DPW
Dated: April 26, 2004
Received: May 6, 2004

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket 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 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the Bi-Directional Doppler Volume Flowmeter, as described in your premarket notification:

Model CSN 01095
Model CSN 01094

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 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 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) 594-4591. 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 Part 807.97). 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 at (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".
If you have any questions regarding the content of this letter, please contact Kachi Enyinna at (301) 443-8262.

Sincerely yours,

Donna R. Vachuer

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

Enclosures

Indications for Use Statement

510(k) Number (if known): K041180

Device Name: Quantix OR device

Indications for use: The Quantix OR Vessel Stabilizer device is intended for intra-operative examinations of blood flow measurements.

Prescription Use ✓ (Per 21 C.F.R. 801.109) OR Over-The-Counter Use____ (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)

Donna R. Vochmel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K041180

1 of 3

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

510(k) No.: K041180

Intended Use: Intra-operative examination of Blood Flow Measurements

Transducer: 4 MHz probe

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)				X						
Intra-operative Neurological										
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

N= New Indication; P = Previously cleared by FDA; E = Added under Appendix E

Additional Comments: _____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna R Ledwell

(Division Sign-Off)

Division of Cardiovascular Devices

510(k) Number K041180

Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

510(k) No.: K041180

Intended Use: Intra-operative examination of Blood Flow Measurements

Transducer: 8 MHz probe

Mode of Operation

Clinical Application	A	B	C	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Color Velocity Imaging	Combined (Specify)	Other (Specify)
Ophthalmic										
Fetal										
Abdominal										
Intra-operative (Specify)	P									
Intra-operative Neurological	P									
Pediatric										
Small Organ (Specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Trans-esophageal										
Trans-Rectal										
Trans-Vaginal										
Trans-Urethral										
Intra-Luminal										
Peripheral Vascular										
Laparoscopic										
Musculo-Skeletal Conventional										
Muscolo-Skeletal Superficial										
Other (Specify)										

N= New Indication; **P = Previously cleared by FDA**; E = Added under Appendix E

Additional Comments:_____

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

Donna P. Bochner

(Division Sign-Off)

Division of Cardiovascular Devices

3083

510(k) Number K041180