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510(k) Summary of Safety and Effectiveness

Zargis Acoustic Cardioscan

Pursuant to §513(i)(3)(A) of the Food, Drug, and Cosmetic Act, Zargis Medical Corporation is required to submit with this Premarket Notification either an"...adequate summary of any information respecting safety and effectiveness or state that such information will be made available upon request of any person." Zargis Medical chooses to submit a summary of information respecting safety and effectiveness.

Trade Name:	Zargis Acoustic Cardioscan (ZAC)
Common Name:	Heart Sound Analyzer
Classification Name:	Phonocardiograph with Waveform Analysis – 21 CFR 870.2390. This device is categorized as DQC and is regulated as Class II.
Submitter Information:	Zargis Medical Corporation 755 College Road East Princeton, NJ 08540 Tel: 609.734.6510 Fax: 609. 734-6565
Summary Prepared By:	Shahram Hejazi, Ph.D. President/CEO
Date Prepared:	March 26, 2004
Predicate Devices:	ELI 200+ Audicor – K031182 2010 Holter Plus Monitor – K010949

Device Description: The ZAC is an electronic auscultatory device intended to acquire, record, and analyze heart sounds. Heart sounds identified are S1, S2 and suspected murmurs.

The complete system is comprised of an electronic stethoscope, a notebook computer, software, a printer and an isolation transformer.

Intended Use:
The Zargis Acoustic Cardioscan, (ZAC), is an electronic auscultatory device, intended to provide support to the physician in the evaluation of heart sounds in patients.

The product will acquire and record the acoustic signals of the heart and analyze these

signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

The device is indicated for use in a clinical setting, by a physician or by trained personnel who are acting on the orders of a licensed physician. It is not intended as a sole means of diagnosis.

The interpretations of heart sounds offered by the Zargis Acoustic Cardioscan are only significant when used in conjunction with physician over-read as well as consideration of all other relevant patient data.

Substantial Equivalence: The ZAC is similar in design/technological characteristics, indications for use, and performance characteristics to the other commercialized devices named above. In addition, non-clinical performance testing has been conducted to demonstrate the performance of the ZAC device and that it meets its intended use.

Safety and Performance: A comprehensive list of verification and validation testing was performed in accordance with Zargis' Design Control procedures.

The ZAC product consists of hardware and software components. The electronic stethoscope, processing platform, and isolation transformer were independently evaluated as hardware components. The printer and interface cabling were verified at the system level.

Software verification was performed at the module and system level. The integrated ZAC system was further evaluated to verify the graphic user interface software and the ZAC system as an integrated product.

Validation of the ZAC was performed to ensure that the ZAC device consistently fulfills its intended use and the needs of the user. A clinical software validation was performed to insure the performance of the heart sound detection algorithm. In addition, usability validation (i.e., simulated use), reproducibility validation, and software component validation were performed.

Conclusion: Based upon the indications for use, technological characteristics and safety and performance testing, the Zargis Acoustic CardioScan has been shown to be substantially equivalent to legally marketed predicate devices under the Federal Food, Drug, and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 6 2004

Zargis Medical Corporation
c/o Shahram Hejazi, Ph.D.
President/CEO
755 College Rd. East
Princeton, NJ 08540

Re: K031517
Trade Name: Zargis Acoustic Cardioscan (ZAC)
Regulation Number: 21 CFR 870.1875, 870.2390
Regulation Name: Stethoscope, Phonocardiograph
Regulatory Class: II (two)
Product Code: DQD, DQC
Dated: March 29, 2004
Received: March 30, 2004

Dear Dr. Hejazi:

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) 594-4648. 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/dsma/dsmamain.html

Sincerely yours,

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): K031517

Device Name: Zargis Acoustic Cardioscan (ZAC)

Indications For Use:

The Zargis Acoustic Cardioscan, (ZAC), is an electronic auscultatory device, intended to provide support to the physician in the evaluation of heart sounds in patients.

The product will acquire and record the acoustic signals of the heart and analyze these signals. The analysis procedure will identify specific heart sounds that may be present. Identified sounds include S1, S2, and suspected murmurs.

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. O'Hara for BDT

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K031517