K970970

9. SMDA Summary of Safety and Effectiveness - "510(k) Summary"

JUN 13 1997

A. Sponsor Information

Manufacturer:	Focus Medical SA 4, Chemin de Maupertuis 38240 Meylan, France
Telephone:	(33)-4-7604-1070 (33)-4-7641-9064 Fax
Contact Person:	Johan Brag
Date Prepared:	February 25, 1997

B. Device Identification

Common/Usual Name	Cardiac Stress and Rest SPECT Imaging Processing Software
Proprietary Name:	CARDIOMATCH®

C. Identification of Predicate Device(s)

CARDIOMATCH® is substantially equivalent to the following previously cleared and currently marketed devices:

General Electric	C-Equal ™	K914527	November 22, 1991
NUC Cardiac	C-Equal	K914296	November 27, 1991

D. Indications for Use

CARDIOMATCH® is a diagnostic software program that quantitatively analyzes myocardial perfusion in patients injected with Cardiolite® (Tc Sestamibi) or Thallium following a rest/stress Single Photon Emission Computerized Tomography (SPECT) acquisition protocol.

E. Device Description

The program automatically determines the alignment parameters for the stress and rest reconstructed MPS SPECT images and, following operator verification of these parameters, performs a size and shape normalization to a template using a published and independently validated 3D image registration method. The normalized images are then compared to a normal distribution and the results of this comparison are used to generate a visual and quantitative representation of the extent and location of perfusion defects.

Results are presented in the form of 3D representation of the normalized images including a visualization of the abnormalities as well as a table indicating the number, extent and location of abnormalities.

F. Marketing history

There has been other diagnostic software programs marketed in the past, in particular CEqual™, which perform similar functions to those performed by CARDIOMATCH®. These programs are used to quantitatively analyze the myocardial perfusion of patients injected with Cardiolite® (Tc Sestamibi) or Tl^{201} , another myocardial perfusion agent. The most widely utilized quantitative programs are the Cedars-Sinai "Bullseye" method, and Emory University and General Electric method embodied in CEqual™. To our knowledge there have been no safety problems with either of these two widely used methods which have been in the marketplace for over the past nine and six years, respectively.

G. Potential Adverse Effect on Health

The intent of the program is to provide the physician with an adjunctive diagnostic tool to aid in the diagnostic interpretation of the patients MPS SPECT studies. It is not meant to replace or eliminate the standard visual analysis of the MPS images. The physician should integrate all of the patient's clinical and diagnostic information, i.e. patient's history, stress and/or rest EKG, quality control images, visual interpretation of the tomographic images, and quantitative results prior to making his final interpretation. This program (as all other diagnostic imaging programs) is not perfect and will be associated with some false positives and false negative results. The physician should be aware of the program's limitations and accuracy when integrating the quantitative results for his final interpretation. Therefore the program has no adverse effect on health since the results represent only a part of the information which the physician will utilize for his final interpretation. The final responsibility for integration of the results and interpretation of the study lies with the physician.

H. Conclusions

The safety of this program has been established through the various stages of software development which included the initial design, coding, debugging, testing and in-house validation. The safety and effectiveness has also been established in an independent validation study on over 50 patients performed at Stanford University. The accuracy results obtained with this program are similar or higher to those obtained with previous quantitative analysis programs. We contend that the method employed for the development and the independent validation of the program (CARDIOMATCH®) have demonstrated its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Jean-Luc Boulnois, Ph.D.
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Wellesley, MA 02181

JUN 13 1997

Re: K970970
CardioMatch
Dated: March 12, 1997
Received: March 17, 1997
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Dr. Boulnois:

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 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) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970910

Device Name: CardioMatch®

Indications For Use:

- Cardiac diagnostic software program to quantitatively analyze myocardial perfusion in patients injected with Cardiolite® or Thallium-201 following a rest/stress SPECT acquisition protocol.

(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 Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970910

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

(Optional Format 1-2-96)