

K980914

JUN 4 1998

ITEM I

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Emory University  
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Contact person: Ernest Garcia, Ph.D.  
Date Summary Prepared: March 9, 1998

2. Medical Device:

Emory Cardiac Tool Box™ (CEqual®, EGS™) - Display and Processing program for gated SPECT myocardial perfusion studies executing on nuclear medicine computer systems.

3. Medical Device Equivalence:

SPECTEF Protocol developed by GE Medical Systems, Ref. 510(k) #: K954874.

4. ~~Device~~ Description:

The Emory Cardiac Tool Box™ (CEqual®, EGS™) is used to display gated wall motion and for quantifying parameters of left-ventricular function from gated SPECT myocardial perfusion studies. These parameters are: ejection fraction, end-diastolic volume, end-systolic volume, myocardial mass and transient ischemic dilatation (TID). This program was developed to run in the IDL operating system environment and can be executed on any nuclear medicine computer systems which supports IDL. The program processes the studies automatically, however, user verification of output is required and manual processing capability is provided.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a program which would allow him to display wall motion and determine measurements of ejection fraction and ventricular volumes from his patients

) gated SPECT myocardial perfusion study. This program serves merely as a display and processing program to aid in the diagnostic interpretation of a patients' study. It was not meant to replace or eliminate the standard visual analysis of the gated SPECT study. The physician should integrate all of the patients' clinical and diagnostic information, i.e. patients' history, stress and/or rest EKG, quality control images, visual interpretation of the gated tomographic images, and quantitative results, prior to making his final interpretation. This comprehensive processing technique (as with all diagnostic imaging) is not perfect, and will be associated with some false positive and false negative results. The expected accuracy of the program can be found in the multicenter trial results listed in the article by Vansant et al (See Item H, Testing & Validation) and the physician should be aware of the accuracy when integrating the quantitative results for his final interpretation. Therefore, this program has no direct 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 interpretation of the study lies with the physician.

#### 6. Marketing History:

) There have been several medical device gated SPECT programs marketed in the past which perform similar functions to those performed by the Emory Cardiac Tool Box™ (CEqual®, EGS™). These programs are all used for the purpose of displaying wall motion and deriving functional parameters for the diagnostic interpretation by a physician. The Emory Cardiac Tool Box™ (CEqual®, EGS™) provides a program which executes in the IDL operating system environment and we believe is substantially equivalent to the SPECTEF Protocol developed by GE Medical Systems K954874. To our knowledge there have been no safety problems with the SPECTEF Protocol program which has been in the marketplace for over two years.

#### 7. Conclusions:

) The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and validation. The effectiveness of the program has been established in phantom and computer simulations studies, in-house trial validations which included an evaluation of left ventricular functional parameter calculations in 217 patients, and in a multicenter trial validation consisting of 80 patients (See Item H, Testing & Validation). We contend that the method employed for the development and the final in-house and multicenter trial validation results of this medical display software program, Emory Cardiac Tool

Box™ (CEqual®, EGS™), have proven its safety and effectiveness. In our opinion the Emory Cardiac Tool Box™ (CEqual®, EGS™) is substantially equivalent to the GE Medical Systems SPECTEF Protocol which has been cleared for marketing. The Emory Cardiac Tool Box™ (CEqual®, EGS™) is intended for the same purpose and raises no new issues of safety or effectiveness.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ernest V. Garcia, Ph.D.  
Emory University School of Medicine  
Emory Center For Positron Emission Tomography  
Emory University Hospital  
1364 Clifton Rd., N.E.  
Atlanta, Georgia 30322

Re: K980914  
Emory Cardiac Tool Box  
Dated: March 9, 1998  
Received: March 11, 1998  
Regulatory class: II  
21 CFR 892.1200/Procode: 90 KPS

Dear Dr. Garcia:

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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/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): K980914

DEVICE NAME: Emory Cardiac Tool Box™ (CEqual® , EGS™)

INDICATIONS FOR USE:

The Emory Cardiac Tool Box™ (CEqual® , EGS™) software program should be used for the quantification of perfusion (CEqual®) and for the display of wall motion and quantification of left-ventricular function parameters from gated TC<sup>99m</sup> SPECT myocardial perfusion studies (EGS™).

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

\_\_\_\_\_  
(Concurrence of CDRH, Office of Device Evaluation (ODE))

Prescription Use ✓ OR Over-The-Counter-Use \_\_\_\_\_  
(Per 21 CFR 801.109) (Optional Format 1-2-96)

David A. Johnson  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K980914