K972509

ITEM I

SUMMARY OF SAFETY AND EFFECTIVENESS

SEP - 8 1997

1. Indications for use:

This software program should be used to quantitatively analyze the myocardial perfusion of patients' who have been injected with Cardiolite® (Technetium Tc99m Sestamibi) for a rest/stress same-day Single Photon Emission Computerized Tomography (SPECT) acquisition protocol. Cardiolite®, Kit for the Preparation of Technetium Tc99m Sestamibi is a myocardial perfusion agent that is useful in the evaluation of ischemic heart disease. Cardiolite®, Kit for the Preparation of Technetium Tc99m Sestamibi is useful in distinguishing normal from abnormal myocardium and in the localization of the abnormality, in patients with suspected myocardial infarction, ischemic heart disease or coronary artery disease. Evaluation of ischemic heart disease or coronary artery disease is accomplished using rest and stress techniques.

Cardiolite®, Kit for the Preparation of Technetium Tc99m Sestamibi is also useful in the evaluation of myocardial function using the first pass technique.

Rest-exercise imaging with Tc99m Sestamibi in conjunction with other diagnostic information may be used to evaluate ischemic heart disease and its localization.

In clinical trials, using a template consisting of the anterior wall, inferior-posterior wall and isolated apex, localization in the anterior or inferior-posterior wall in patients with suspected angina pectoris or coronary artery disease was shown. Disease localization isolated to the apex has not been established. Tc99m Sestamibi has not been studied or evaluated in other cardiac diseases.

It is usually not possible to differentiate recent from old myocardial infarction or to differentiate recent myocardial infarction from ischemia.

2. Device Description:

This medical device (CEqual®) is a diagnostic software program that quantitatively analyzes the myocardial perfusion of patients' injected

with Cardiolite® (^{99m}Tc Sestamibi) following a rest/stress same-day SPECT acquisition protocol. The algorithm automatically determines the processing parameters and, following operator verification of these parameters, samples the myocardium using maximum count profiles. These stress and rest profiles are then used to generate relative count "raw data" polar maps. In addition, the profiles are compared to a normal data base and the results of this comparison are used to generate quantitative stress and rest polar maps which indicate defect extent, severity, and reversibility for all abnormal perfusion areas of the patients' study. The final results are presented in the form of polar maps as well as a table indicating the % abnormal pixels in territories supplied by the left anterior descending, left circumflex, and right coronary arteries.

3. Marketing History:

There have been other diagnostic programs marketed in the past which perform similar functions to those performed by CEqual®. These programs were used to quantitatively analyze the myocardial perfusion of patients' injected with Tl^{201}, another myocardial perfusion agent. The most widely utilized Tl^{201} quantitative programs are the Cedars-Sinai and General Electric's "Bullseye" methods. To our knowledge there have been no safety problems with either of these two methods which have been in the marketplace for over the past five years. In addition, the CEqual® program executing on the Siemens and General Electric computer systems have been in the marketplace since October 1992 with no safety problems reported.

4. Potential Adverse Effect On Health:

The intent of this program was to provide the physician with an adjunctive diagnostic tool to aid in the diagnostic interpretation of the patients' Cardiolite® same-day study. It was not meant to replace or eliminate the standard visual analysis of the Cardiolite® images. 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 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 accuracy of the program is listed in the operators manual 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 integration of the results and interpretation of the study lies with the physician.

5. Conclusions:

The safety of this program has been determined through the various stages of software development which included the code translation, debugging, testing, and in-house validation. The effectiveness of the program has been established in a prospective validation which included 35 patients acquired and processed at another institution. The accuracy results obtained with this program are similar to those obtained with previous quantitative analysis programs of the Tl-201 myocardial perfusion agent (1,2) and Cardiolite® (3,4). We contend that the method employed for the development and the final multicenter trial validation results of this quantitative software program (CEqual®) have proven its safety and effectiveness.

References

1. Depasquale EE, Nody AC, DePuey EG, et al: Quantitative rotational thallium-201 tomography for identifying and localizing coronary artery disease. Circulation 77:316-327, 1988.

2. Van Train K, Maddahi J, Berman DS, et al: Quantitative Analysis of Tomographic Stress Thallium-201 Myocardial Scintigrams: A Multicenter Trial. J Nucl Med 31:1168-1179, 1990.

3. Van Train KF, Areeda J, Garcia EV, et al: Quantitative same-day rest-stress Technetium-99m sestamibi SPECT: definition and validation of stress normal limits and criteria for abnormality. J Nucl Med 1993; 34:1494-1502.

4. Van Train KF, Garcia EV, Maddahi J, et al: Multicenter Trial Validation for Quantitative Analysis of Same-Day Rest-Stress Technetium-99m-Sestamibi Myocardial Tomograms. J Nucl Med 1994; 35:609-618.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 8 1997

Kenneth F. Van Train
President
NucCardiac Software, Inc.
21520-"G" Yorba Linda Blvd., Suite 420
Yorba Linda, CA 92887

Re: K972509
C Equal - Quantitative Analysis SPECT Software
Dated: July 2, 1997
Received: July 3, 1997
Regulatory Class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Van Train:

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 Current Good Manufacturing Practice requirement, 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/dsmamain.html".

Sincerely yours,

William Yin

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): K972509

Device Name: CEqual for Toshiba Corporation (Diagnostic Software)

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	YES	NO	Energy Range (keV)
A. Planar imaging		X	
B. Whole body imaging		X	
C. Tomographic imaging (SPECT) for non Positron emitter	X		140 keV
D. Positron imaging by coincidence		X	
E. Positron imaging without coincidence		X	
F. Other indication(s) in the device label, but not included in above list	None		

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K972509