K060020

JAN 20 2006

510(k) SUMMARY SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
540 Alder Dr.
Milpitas, CA 95035

Contact: Coleman A. Coleman
Tel: (408) 468-3051
Fax: (408) 468-3050

B. Device Trade Name: AutoQUANT® Plus

Common Name:	Nuclear Medicine Software Application
Classification Name:	Emission Computed Tomography System
Device Class:	21 CFR 892.1200, Class II
Product Code:	90 KPS

C. Date prepared: December 16, 2004

D. Predicate Device (s):

Manufacturer	Product Name	510(k) No.
ADAC Laboratories	AutoQUANT® Plus	K040326

E. Intended Use:

AutoQUANT® Plus applications are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. AutoQUANT® Plus may be used in multiple settings including the hospital, clinic, doctors office, or remotely via dial up. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

F. Device Description:

AutoQUANT® Plus (K040326) was composed of the following applications: AutoQUANT® (K040326) [AutoQUANT integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis], Quantitative Blood Pool SPECT (QBS) and optionally QARG (for reporting purposes).

The modified AutoQUANT® Plus is a suite of applications for the processing and review of Cardiac SPECT and PET datasets. AutoQUANT® Plus is composed of the following applications: AutoQUANT® (K040326) [AutoQUANT integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis]. AutoQUANT Plus will be marketed as AutoQUANT NM, which combines the following two separate sets of

functionality: AutoQUANT – optimized for SPECT studies and QPET – optimized for PET studies. Both sets of functionality offer a comprehensive application suite that includes QGS (Quantitative Gated SPECT) and QPS (Quantitative Perfusion SPECT) applications. This allows automatic processing and review of quantitative and qualitative information generated by nuclear medicine studies. QPET also includes viability quantification and two additional databases (rubidium and ammonia) for processing PET studies. AutoQUANT NM can also be purchases separately as AutoQUANT (for SPECT study data) or QPET (for PET study data). Purchasable Options consist of Quantitative Blood Pool SPECT (QBS), QARG (for reporting purposes), Fusion (SPECT/CT/CTA and/or PET/CT/CTA, and Prone-Supine (Prone+) for SPECT studies.

AutoQUANT® is a software application designed to enable an automated, comprehensive review and quantification of Cardiac SPECT data. AutoQUANT® integrates 2 functionalities, Quantitative Perfusion SPECT (QPS) and Quantitative Gated SPECT (QGS) into a single application for LV (Left Ventricle) extraction and analysis. AutoQUANT® provides a tool to review and quantify all types of Cardiac SPECT data sets (perfusion and/or gated) to determine the location, orientation, and anatomical extent of the left ventricle of the heart, to construct 3D contour maps of the heart, and to calculate the heart volume (for the left ventricular wall), the lung/heart ratio, and transient ischemic dilation (TID). Physicians use this information to assess the anatomical and physiological functionality of the heart and analyze the presence of myocardial defects through comprehensive imaging modalities. A new Phase toggle on the QGS page gives access to phase information for gated datasets. Stress-Rest Registration is a direct method for detecting changes between stress and rest images. It is a practical and fully automatic algorithm for quantification of stress-induced changed from paired stress and rest scans and does not use protocol-specific databases. A new technique to create cardiac "motion-frozen" perfusion or viability images, by warping ECG-gated images to the end-diastolic position has been added. Such "motion-frozen" perfusion and viability images have improved resolution and contrast by removing blurring effect caused by cardiac motion. Prone-supine quantification allows quantification of perfusion on prone images as well as combined quantification of prone/supine datasets by applying heuristic rules, which allow automatic elimination of image artifacts based on the relative defect locations on prone and supine images. The new shape index parameter defines 3D left ventricular (LV) geometry derived from LV contours in end systolic and end diastolic phases.

The AutoQUANT application provides Normal Files database for stress, rest, and gender criteria for Dual Isotope and Mibi Mibi (Tc-Sestamibi). The new version of QPS includes the simplified algorithm for the quantification of myocardial perfusion, using normal limits created from studies of low-likelihood normal patients only. The new algorithm has been validated in a large group of patients demonstrating equivalent diagnostic performance despite the use of simplified normal limits. In addition, to Dual Isotope and Mibi Mibi using the new simplified algorithm, the following additional databases are being provided Vantage MibiMibi, Thallium Stress/Rest, Astonish ½ Time Dual, and Astonish ½ Time Mibi. Optional Normals databases offered are Rubidium for PET, Ammonia for PET. QPS provides the ability for User Generated Normal Files using the simplified method. The new version of QPS also includes a new variable, Total Perfusion Deficit (TPD), which combines defect extent and severity values. For backward compatibility reasons, the old QPS perfusion quantification method, which displays individual defect extent and

severity values, can be accessed by checking off PFQ option in the QPS Application Defaults. All the functional QGS values (ejection fraction, LV volumes etc) and contour definitions are the same as before.

Quantitative Blood Pool SPECT (QBS) is an optional application. QBS is an interactive standalone software application for the automatic segmentation and quantification of gated short axis blood pool (red blood cells, RBC) SPECT. The application can be used for automatic generation of left and right ventricular endocardial surfaces and valve planes from three-dimensional (3D) gated short axis blood pool images; automatic calculation of left and right ventricular volumes and ejection fractions; calculation and display of polar maps representing wall motion and parametric values (FFH amplitude and phase); two-dimensional (2D) image display using standard American College of Cardiology (ACC) cardiac SPECT conventions; and 3D image display. It also provides the following functionalities: ability to combine isosurfaces extracted from the data with the calculated endocardial surfaces in various ways (endocardial borders displayed as wireframes, shaded surfaces, both, or parametric); ability to map parametric values (First Fourier Harmonic (FFH) amplitude and phase) on the surfaces; ability to display parametric images (FFH amplitude and phase) for gated planar, gated raw projections and gated short axis images; ability to display cine loops of the original images; ability to generate count-based quantitative values using the automatically- and semi automatically-computed surfaces as ROIs and user-selectable thresholds; ability to generate and display phase histograms for FFH phase images and to display the mean and standard deviation of the peaks corresponding to atrial and ventricular voxels. After ventricular segmentation, a phase histogram for each ventricle is also computed and displayed; and ability to display normalized images for all gated images (i.e., images that do not exhibit count drop-off caused by arrhythmia). In addition, QBS supports manual identification of the left-ventricular (LV) region, to separate it from the right ventricle (RV) in cases where the automatic algorithm fails or returns unsatisfactory results; ability to generate filling rates from interpolated time-volume curves; and the ability to rotate, zoom, and cine surfaces.

The ability to load and display PET, CT, CTA datasets in AutoQUANT® Plus have been added as an option. Qualitative displays are now provided functional PET data and CT/CTA anatomical datasets. In addition, nuclear image fusion package has been added for both SPECT/CT and PET/CT hybrid applications. A SPECT/CT fusion package including SPECT/CT/CTA Fusion Page, that allows for display of segmented and labeled coronary vessels with perfusion SPECT 3D data. A PET/CT fusion package including PET/CT/CTA Fusion Page, that allows for display of segmented and labeled coronary vessels with PET 3D data. Functionality includes orthogonal planes using alpha blending, roving window and synchronized cursor. It allows users to perform quality control of SPECT/CT/CTA or PET/CT/CTA alignment and has generic multimodality fusion capabilities. This feature provides display of fused images in a visual format. Additionally, included for PET analysis is the Hibernating Myocardium Assessment (mismatch and viability); This module allows quantitative assessment of "hibernating myocardium" by quantification of changes between PET perfusion and viability images in hypo-perfused area. Scar and Mismatch parameters are reported as a percentage of the Left Ventricle and are displayed in polar coordinates or a 3D surface display.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 20 2006

ADAC Laboratories, Inc.
% Mr. Morten S. Christensen
Staff Engineer & FDA Office Coordinator
Medical Device Services
Underwriters Laboratories, Inc.
455 East Trimble Road
SAN JOSE CA 95131

Re: K060020
Trade/Device Name: AutoQUANT® Plus
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulatory Class: II
Product Code: KPS
Dated: January 3, 2006
Received: January 4, 2006

Dear Mr. Christensen:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510 (k) NUMBER (IF KNOWN): K060020

DEVICE NAME: AutoQUANT® Plus

SPONSOR NAME: ADAC Laboratories

INDICATIONS FOR USE:

AutoQUANT® Plus applications are intended to enable an automated display, review, and quantification of Nuclear Medicine Cardiology medical images and datasets. AutoQUANT® Plus may be used in multiple settings including the hospital, clinic, doctors office, or remotely via dial up. The results provided should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

(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. Seguson
(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K060020