

MAY 6 1998

AutoQUANT, Quantitative Perfusion SPECT (QPS), & Quantitative Gated SPECT (QGS)
ADAC Laboratories
510(k) Premarket Notification

Appendix VIII, 510(k) Summary of Safety and Effectiveness Data

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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

K980715

A. Submitted By: ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035
Tel: (408) 321-9100
Fax: (408) 321-9686

Contact Person: Dennis Henkelman at address above

B. Device Trade Name: AutoQUANT
Quantitative Perfusion SPECT (QPS)
Quantitative Gated SPECT (QGS)
Common Name: Gamma Camera System
Classification Name: System, Emission Computed Tomography

C. Predicate Device: ADAC CEQUAL®
Sopha Sophy NXT

D. Device Description:

AutoQUANT is a software application designed to enable a fully automated, comprehensive review and quantification of Cardiac SPECT data within a suite of applications. AutoQUANT can operate as an independent single application or can be integrated into an application containing Quantitative Perfusion SPECT (QPS) and/or Quantitative Gated SPECT (QGS). 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.

Quantitative Perfusion SPECT (QPS) is a software application designed for the review and quantification of myocardial perfusion SPECT short axis data. QPS can operate as an independent single application or as an embedded function packaged with AutoQUANT. Using the QPS application, myocardial rest and stress short axis projections (standard and gated Cardiac SPECT) can be reviewed and compared, the extent and volume of cardiac defects can be calculated, and 3D and 2D perfusion maps can be generated. The QPS application can also be used to create a user-definable Normal database (with definable normal limits) for review, quantification, and comparison.

Quantitative Gated SPECT (QGS) is a software application designed to view and analyze processed SPECT short axis or gated short axis data sets. QGS can operate as an independent single application or as an embedded function packaged with AutoQUANT. Using the QGS application, myocardial gated short axis projections can be reviewed and compared, the extent and severity of cardiac defects can be calculated, and 3D and 2D wall thickening, wall motion and regional ejection fraction maps can be generated. The application can be used to display the left ventricular endocardial and epicardial surfaces; polar maps indicating perfusion, wall thickening, wall motion, and regional ejection fraction; standard cardiac SPECT short axis and horizontal slices; and 3D cardiac surfaces and volumes from gated SPECT data. When using gated SPECT data, the left ventricular volume and left ventricular ejection fraction (LVEF) can be automatically calculated or regions may be manually specified for calculation. When using non-gated short axis SPECT data, the left ventricular volume can be calculated automatically or manually.

E. Indications for Use:

The AutoQUANT, Quantitative Perfusion SPECT (QPS), and Quantitative Gated SPECT (QGS) applications are intended to enable a fully automated review and quantification of Cardiac SPECT data.

F. Technological Comparison:

The AutoQUANT, QPS, QGS, ADAC CEQUAL, and Sopha Sophy NXT Cardiac Software applications have similar indications for use and utilize the same type of data sets for analysis and calculation of data. The ADAC QPS, QGS, CEQUAL, and Sophy NXT Cardiac Software perform the same calculations and analyses on the data sets.

II. Testing

Testing was conducted to demonstrate that each software application functioned as per its specifications. All tests passed with the actual results matching the expected results.



MAY 6 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Dennis W. Henkelman
Director, Regulatory Affairs
and Quality Assurance
ADAC Laboratories
540 Alder Drive
Milpitas, CA 95035Re: K980715
AutoQUANT (Gamma Camera System)
Dated: February 23, 1998
Received: February 24, 1998
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Henkelman:

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 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

INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

Device Name: AutoQUANT
Quantitative Perfusion SPECT (QPS)
Quantitative Gated SPECT (QGS)

Sponsor Name: ADAC Laboratories

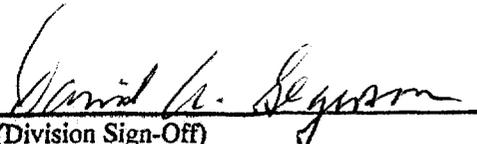
Indications for Use

The AutoQUANT, Quantitative Perfusion SPECT (QPS), and Quantitative Gated SPECT (QGS) applications are intended to enable a fully automated review and quantification of Cardiac SPECT data.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
Over-The-Counter Use


David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K980715