K022428

ADMINISTRATIVE INFORMATION

AUG 0 6 2002

I. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

A. Submitted By:

ADAC Laboratories
540 Alder Drive
Milpitas, California 95035

Tel: (408) 468-3051
Fax: (408) 468-3050

Contact Person: Coleen Coleman
At address above

B. Device Trade Name: Quantitative Blood Pool SPECT (QBS)
Common Name: Nuclear Medicine Software Application
Classification Name: Image Processing System (Computer)

C. Predicate Device(s):

Manufacturer	Product Name	510(k) No.
ELGEMS Ltd.	QPS/BPGS/MoCo Processing Applications for eNTEGRA™ Workstation	K003264

D. Device Description:

Quantitative Blood Pool SPECT (QBS) is a standalone software application for the display and analysis of gated short axis blood pool (red blood cells, RBC) SPECT datasets. The results provided by QBS should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices. QBS provides the following functionality:

- 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.
- Two-dimensional (2D) image display using standard American College of Cardiology (ACC) cardiac SPECT conventions.

- 3D image display. Ability to combine isosurfaces extracted from the data with the calculated endocardial surfaces in various ways (endocardial borders displayed as wireframes, shaded surfaces or both).

- Ability to support 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 rotate, zoom and cine surfaces.

- Calculation and display of polar maps representing wall motion.

E. Indications for Use:

Quantitative Blood Pool SPECT (QBS) is a standalone software application for the display and analysis of gated short axis blood pool (red blood cells, RBC) SPECT datasets. The results provided by QBS 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. Technological Comparison:

The Quantitative Blood Pool SPECT (QBS) and the QPS/BPGS/MoCo Processing Applications for eNTEGRA Workstation (K003264) have similar indications for use and overall function and perform in a similar manner with respect to data display and analysis.

II. CONCLUSIONS

QBS is substantially equivalent to BPGS contained in the ELGEMS Ltd. QPS/BPGS/MoCo Processing Applications (K003264) previously cleared by FDA. QBS™ and BPGS (K003264) have the same indications for use and overall function and perform in a similar manner with respect to processing and display of short axis Blood Pool Gated SPECT imaging.

BPGS software application contained in the predicate device (K003264) is similar to the ADAC Quantitative Blood Pool SPECT (QBS). BPGS (K003264) and QBS both have automatic calculation of left and right ventricular volumes and ejection fractions, provide (3D) models, and have calculation and display of polar maps. QBS has similar indications for use and overall function and perform in a similar manner with respect to data display and analysis as the predicate device BPGS (K003264). Therefore, this premarket notification has demonstrated substantial equivalence as defined and understood in the Federal Food, Drug, & Cosmetic Act and its amendments.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 6 2002

ADAC Laboratories
% Michael Kwan, Ph.D.
Office Coordinator
Underwriters Laboratories, Inc.
1655 Scott Boulevard
SANTA CLARA CA 95050-4169

Re: K022428
Trade/Device Name: Quantitative Blood Pool SPECT (QBS)
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: July 24, 2002
Received: July 25, 2002

Dear Dr. Kwan:

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 (PMA), it may be subject to 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 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:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.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): K022428

Device Name: Quantitative Blood Pool SPECT (QBS)

Sponsor Name: ADAC Laboratories

Indications for Use:

Quantitative Blood Pool SPECT (QBS) is a standalone software application for the display and analysis of gated short axis blood pool (red blood cells, RBC) SPECT datasets. The results provided by QBS should be reviewed by qualified healthcare professionals (e.g., radiologists, cardiologists, or general nuclear medicine physicians) trained in the use of medical imaging devices.

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 and Radiological Devices
510(k) Number K022428

Prescription Use ☑
Over-The-Counter Use ☐