OCT 1 1999

K992317

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS DATA

I. General Information

A. Submitted By:

ADAC Laboratories
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Milpitas, CA 95035
Tel: (408) 468-3989
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Contact Person: Dennis W. Henkelman at address above

B. Device Trade Name: AutoSPECT Plus with InStill Motion Correction
Common Name: Gamma Camera Systems
Classification Name: System, Emission Computed Tomography

C. Predicate Device: SMV STATIS™
SMV MyoSPECT with ReOrient Express

D. Device Description:

The AutoSPECT Plus with InStill Motion Correction software option enables automatic processing of one or more cardiac SPECT, gated SPECT, Vantage SPECT, MCD, or MCD-AC cardiac data sets. In addition, AutoSPECT Plus with InStill Motion Correction enables the manual processing of one or more SPECT, gated SPECT, Vantage SPECT, MCD, or MCD-AC data sets. The basic data processing algorithms utilized by AutoSPECT Plus with InStill Motion Correction are ones which have been utilized in previously cleared ADAC products.

For automatically processing cardiac data sets, AutoSPECT Plus with InStill Motion Correction provides three options. The first of these options, "Auto All", automatically determines the reconstruction limits, reconstructs and reorients the cardiac data sets and creates the short axis, horizontal long axis and vertical long axis data sets. The second option, "Auto Recon", automatically determines the reconstruction limits and reconstructs the cardiac data sets. The third option, "Auto Reorient", automatically reorients the cardiac transverse data sets. If necessary, AutoSPECT Plus with InStill Motion Correction reconstructs the data sets prior to re-orientation.

AutoSPECT Plus with InStill Motion Correction software also allows the user to process noncardiac SPECT, Vantage, MCD, or MCD-AC data sets. In this case, the operator manually positions the reconstruction limit lines to reconstruct transverse data sets. If necessary, the data set can be reoriented by manually positioning the Azimuth and elevation lines to the desired location.

The AutoSPECT Plus with InStill Motion Correction software will also process groups of SPECT data sets in a batch mode fashion. Once the operator has selected the data sets and determined the processing method (i.e. Auto All, Auto Recon, Reorient, or Reconstruct), AutoSPECT Plus with InStill Motion Correction processes the first data set followed by all remaining data sets without further interaction from the operator.

E. Indications for Use:

The AutoSPECT Plus with InStill Motion Correction option to the ADAC Gamma Camera Systems produces images which depict anatomical density of the patient. This system is intended to provide enhancements of gamma camera emission images by automating previously manual image processing functions and providing manual and automated motion correction.

F. Technological Comparison:

The AutoSPECT Plus with InStill Motion Correction, SMV STASIS™ and SMV MyoSPECT with ReOrient Express devices have the same indications for use and operating principles.

II. Testing

Images were processed using the AutoSPECT Plus with and without InStill Motion Correction.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 1 1999

Dennis W. Henkelman, R.A.C.
Director, Regulatory Affairs & Quality Assurance
ADAC Laboratories
540 Alder Drive
Milipitas, California 95035

Re: K992317
AutoSPECT Plus with InStill Motion Correction
Dated: July 8, 1999
Received: July 9, 1999
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 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). 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,

CAPT Daniel G. Schultz, M.D.
Acting 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): K992317

Device Name: AutoSPECT Plus with InStill Motion Correction

Sponsor Name: ADAC Laboratories

Indications For Use:

The AutoSPECT Plus with InStill Motion Correction option to the ADAC Gamma Camera Systems produces images which depict anatomical density of the patient. This system is intended to provide enhancements of gamma camera emission images by automating previously manual image processing functions and providing manual and automated motion correction.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☑
Over-The-Counter Use ☐

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992317