K041782

AUG 16 2004

ITEM I

510(k) SUMMARY

Safety and Effectiveness

1. Medical Device Establishment:

Areeda Associates Ltd
Registration No. 2030898
Owner Operator I.D. 9029223
Device Regulation Number: 892.1200
Product Code: 90 LLZ
Classification Panel: Radiology
Voice: (323) 653-5515, FAX: (323) 653-5514
Contact Person: Joseph Areeda or Kenneth Van Train
Address: Areeda Associates, Ltd.
516 N. Curson Avenue
Los Angeles, CA 90036
Date Summary Prepared: May 17, 2004

2. Medical Device:

SeeMor™ 5.0 - Medical Imaging Display & Processing program executing on personal computer systems with ReconTool™.

3. Medical Device Equivalence:

AutoSPECT Plus developed by ADAC Laboratories Ref. 510(k) #: K992317.

4. Device Description:

The SeeMor™ 5.0 medical viewing application is used for transfer and viewing diagnostic medical images. The program provides the capabilities of manipulating the images being displayed with the command options including: clipping, window/level adjustment, magnification, pan, relate, add, delete, next, cine, lock, select, view, flip vertical/horizontal, set color table, orthogonal view reconstruction, cascade, tile, and reset. The ReconTool™ processing application within Seemor™ 5.0 can be used to reorient and apply tomographic reconstruction to SPECT & PET gated and ungated myocardial perfusion image data sets.

5. Intended Use and Potential Adverse Effect on Health:

The intended use of this program was to provide the physician with a display program which would allow for the transfer, remote viewing and interpretation of medical images. In addition, an optional feature has been added to allow for the reorientation and reconstruction of SPECT & PET gated and ungated myocardial perfusion image data sets. This program serves merely as a display program to aid in the diagnostic interpretation of a patients' study and to provide reorientation and reconstruction capability of SPECT & PET iamges. It does not provide any diagnostic interpretive output other than the display of the images. Therefore, this program has no direct adverse effect on health since it is only providing a means of displaying the medical images for the physician. The final responsibility for interpretation of the study lies with the physician.

6. Marketing History:

There have been multiple medical device programs marketed in the past which perform similar functions to those performed by SeeMor™ with the ReconTool™ . These programs are all used for the purpose of reorienting and reconstruction of SPECT & PET myocardial perfusion image data sets. The SeeMor™ 5.0 program with ReconTool™ provides a program which executes on non-propriety hardware (such as Windows PC or Macintosh) and we believe is substantially equivalent to the AutoSPECT Plus developed by ADAC Laboratories K992317. To our knowledge there have been no safety problems with the AutoSPECT Plus medical display program which has been in the marketplace for over four years.

7. Conclusions:

The safety of this program has been determined through the various stages of software development which included the initial design, coding, debugging, testing, and in-house validation. The effectiveness of the program has been established in an in-house trial validation which included an evaluation of 20 patients. We contend that the method employed for the development and the final in-house trial validation results of the SeeMor™ medical software program (with ReconTool™) have proven its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2004

Mr. Joseph Areeda
President
Areeda Associates Ltd.
516 N. Curson Ave.
LOS ANGELES CA 90036-1814

Re: K041782
Trade/Device Name: SeeMor™ Image Display Program
Regulation Number: 21 CFR 892.1200
Regulation Name: Emission computed tomography system
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ and KPS
Dated: June 15, 2004
Received: July 1, 2004

Dear Mr. Areeda:

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 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 the 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" (21CFR Part 807.97) you may obtain. 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

510(k) NUMBER (IF KNOWN): K041782

DEVICE NAME: SeeMor™ 5.0 Image Display Program

INDICATION FOR USE:

SeeMor™ 5.0 software program should be used for the transfer, display and image manipulation of multimodality diagnostic medical images and for the reorientation, and filtered backprojection reconstruction of SPECT & PET gated and ungated myocardial perfusion data.

(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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K041782