K973653

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ITEM I

510(k) SUMMARY

DEC 12 1997

Safety and Effectiveness

1. Medical Device Establishment:

Areeda Associates Ltd
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Los Angeles, CA 90036
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Contact person: Joseph Areeda or Kenneth Van Train
Date Summary Prepared: September 24, 1997

2. Medical Device:

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

3. Medical Device Equivalence:

MedVision™ Imaging Software developed by Evergreen Technologies, Inc., Ref. 510(k) #: K924178.

4. Device Description:

This medical device (SeeMor™) is a display program for viewing diagnostic medical images. The program provides the capabilities of manipulating the images being displayed with the following command options: 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.

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 remote viewing and interpretation of

medical images. This program serves merely as a display program to aid in the diagnostic interpretation of a patients' study. 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 display programs marketed in the past which perform similar functions to those performed by SeeMor™. These programs are all used for the sole purpose of displaying medical images for the diagnostic interpretation by a physician. The SeeMor™ program provides a program which executes on non-propriety hardware (IBM PC or Macintosh) and we believe is substantially equivalent to the MedVision Viewer developed by Evergreen Medical Technologies K924178. To our knowledge there have been no safety problems with the MedVision Viewer medical display program which has been in the marketplace for over four years. In addition, we are not aware of any problems on any of the proprietary medical display programs which have been in the marketplace for over 20 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 25 patients. We contend that the method employed for the development and the final in-house trial validation results of this medical display software program (SeeMor™) have proven its safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 12 1997

Joseph Areeda
President
Areeda Associates, Ltd.
516 N. Curson Ave.
Los Angeles, CA 90036-1814

Re: K973653
SeeMor™ (Image Processing System)
Dated: September 24, 1997
Received: September 25, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

Dear Mr. Areeda:

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 requirement, 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/dsmamain.html".

Sincerely yours,

Lillian Yin

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

510(k) Number (if known): K973653

Device Name: SeeMor - Display & Processing Program Executing on Personal Computers

Indications For Use:

The SeeMor™ software program should be used for the display and image manipulation of multimodality diagnostic medical images.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number ____