K993530

DEC 15 1999

General Purpose Radiological Image Display System
File: 510ksum.doc
Date: Dec. 7, 1999

510(k) Summary

System 2100 is a software program intended as a medical image display system that performs the following functions:

1. Displays medical images.
2. Can provide image processing and enhancements, such as contrast control, edge enhancement.
3. Can stack images from a series to form a three dimensional model.
4. Provides outlining and segmentation tools.
5. Can display outlined and segmented structures in three dimensional perspective views.
6. Provides generic support for stereotactic frames with the determination of the stereotactic coordinates of a point.
7. Provides three methods for solving for the transformation of coordinates between two image series, referred to as image fusion. The three methods are using stereotactic frames, using common points, and using common surfaces.
8. Can serve as a front end to other systems that do not have image fusion or segmentation methods.
9. Can be used as a means for printing hardcopy of images, reformatted images, and 3d perspective views.
10. Can serve as an object library for university research centers and other vendors (who are then responsible for the use and complying with federal and state regulations).

The system is intended for use by any health practitioner who may have need of the functions provided.

The capabilities provided in System 2100 can be found in a wide variety of present medical devices. Most CT and MRI consoles (General Electric Medical Systems, Rochester, NY) provide the means to view the images generated by those devices and will allow the reformatting of images in other planes.

Image fusion and support for stereotactic frames is provided by the product Xknife sold by Radionics, 2 Brookline Place, Suite 205, Brookline, MA 02146. Another product that supports a stereotactic frame and provides image fusion is Gamma Plan from Elekta Instruments, Inc., 3155 Northwoods Parkway, Norcross, Georgia, 30071.

System 2100 is similar to a predicate image display system call Precision View sold by Elekta Oncology (at the same address above for Elekta Instruments). Precision View has outlining and segmentation methods, image fusion, and may down load region of interest contours in DICOM files to a radiation therapy treatment planning system.

Outlining and solid model displays can be found in most therapy planning systems today, such as Render Plan 3-D, sold by Elekta Oncology (address above); Treatment planning and CT simulation systems sold by Prowess Systems, 1370 Ridgewood Dr., Suite 20, Chico, CA 95973; CMS Focus sold by Computerized Medical Systems, Inc., 1195 Corporate Lake Dr., St. Louis, MO 63132; Penicle sold by ADAC Laboratories, 540 Alder Dr., Milpitas, CA 905035; Plato sold by Nucletron Corp., 7080 Columbia Gateway Dr., Columbia, MD 21046.

Document approved by: Wendel Dean Renner

Wendel Dean Renner

Title: President Date: Dec. 7, 1999

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 5 1999

Wendel Dean Renner
Math Resolutions LLC
5975 Gales Lane
Columbia, MD 21045

Re: K993530
System 2100 (Radiological Display Software)
Dated: October 15, 1999
Received: October 18, 1999
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Renner:

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

510(k) NUMBER (IF KNOWN): K993530

DEVICE NAME: System 2100

INDICATIONS FOR USE:

see attached statement

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-U
(Per 21 CFR 801.109) (Optional Format

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K993530

510(k) Number: K993530

file: induse2.doc

Device Name: System 2100

Indications For Use:

The system is intended for use by any health practitioner who has the need for any of the below functions:

1. The software may be used to display medical images. The user may adjust the contrast of the images and image process the images with an edge enhancement algorithm. The user can zoom in on a region of an image, enlarging that region on the display screen. Other image processing functions may be added in the future to allow the user to enhance some aspect of an image, such as histogram processing, spatial filtering, frequency filtering.

2. Images from the same series can be stacked to form a three dimensional model. This will allow the use of the system to reformat images in other planes, such as coronal and sagittal planes.

3. Outlining tools are provided to use the system to outline regions of interest. These outlines may be combined to define three dimensional shapes which can be viewed in three dimensional perspective views.

4. The region of interest outlines may be written back to DICOM formatted image files for export to other systems.

5. The system can be used to determine the stereotactic coordinates of a point located on an image when a stereotactic system is employed.

6. The system may be used to provide support for any stereotactic system that consists of fixed rods which can be uniquely located on CT and MRI images.

7. The system may be used to solve for the transformation between two images sets, referred to as image fusion.

8. A region of interested outlined on one image set may be transferred to a fused image set.

9. The system may be used as a front end to other systems that do not provide image fusion. An example would be outlining a region of interest on MRI scans, transferring the outlines to CT scans, and writing the outlines back into DICOM image files. Those files can be available to other systems such as a radiation therapy treatment planning system.

10. The system may be used to print hardcopy images of selected images, reformatted images, and three dimensional perspective views.

11. Image segmentation tools are provided to create three dimensional structures for viewing in three dimensional perspective views.

The intention is also to provide these basic functions as a C++ object library to any party that may wish to use the library to build their own applications. Those customers will be completely responsible for the integration, testing, use of the end product that they produce, and compliance with federal and state regulations.

Document approved by: Wendel Dean Renner Wendel Dean Renner

Title: President Date: Dec. 7, 1999