K053301

5. 510(k) Summary

FEB 3 2006

Submitter:	Cedara Software Corp.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa
Telephone:	(905) 672-2100
Date:	November 25, 2005
Trade Names:	Cedara I-Response™; Cedara PET/CT™
Common Name:	Medical image processing software
Classification Name:	Picture archiving and communications system
Predicate Devices:	Cedara I-SoftView, 510(k) No. K040468 Siemens syngo TrueD, 510(k) No. K041484
Device Description:	The Cedara I-Response and Cedara PET/CT software products are line extensions to Cedara's medical image processing workstation product, Cedara I-SoftView™. The products are designed to facilitate the oncology or other clinical specialty workflow by comparing medical imaging data from different modalities and/or from different time points. The products are able to coregister functional MRI, PET, SPECT, CT, or other modality datasets, segment out Regions of Interest (ROI), and calculate, display, and report relative differences in Apparent Diffusion Coefficient (ADC), Standardized Update Value (SUV), or other values within those regions. The products can be used as standalone applications or can be "plugged in" and launched from within other applications such as Cedara I-SoftView, or from another workstation or console.
Indications for Use:	Two and three dimensional image review, manipulation, analysis and therapy planning capabilities that support image management display needs in the medical environment from multiple locations within and outside the hospital. Diagnostic Review Workstations - Assists medical professionals

including but not limited to radiologists, surgeons, oncologists, neurologists, and cardiologists in conducting primary diagnostic review and planning through the flexible and interactive manipulation of multi-modality softcopy images.

Two and three-dimensional image coregistration (fusion) and segmentation of multiple imaging modality data including but not limited to functional MRI, PET, SPECT, and CT for user-selected regions of interest taken at different time points or generated using different scanning protocols.

Detailed measurement and reporting features assist clinicians in assessing and documenting changes in regions of interest such as pathologies (e.g., tumors, abscesses, AVMs), or other anatomical structures. The software can help track changes in morphology, functional activity, or other responses that may occur as a result of treatment therapy or disease progression.

Comparison to Predicate:

The intended use and technological characteristics of Cedara I-Response and Cedara PET/CT software are substantially equivalent, in the opinion of Cedara Software Corp., to those of the predicate devices and do not pose any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 3 2006

Carol Nakagawa, B.Sc., RAC
Sr. Manager, Quality and Regulatory
Cedara Software Corp.
6509 Airport Road
Mississauga, Ontario, L4V 1S7
CANADA

Re: K053301
Trade/Device Name: Cedara I-Response™ and Cedara PET/CT™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications systems
Regulatory Class: II
Product Code: LLZ
Dated: November 25, 2005
Received: November 28, 2005

Dear Ms. Nakagawa:

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 (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 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.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

510(k) Number (if known): K053301

Device Name: **Cedara I-Response™ and Cedara PET/CT™**

Indications For Use:

Two and three dimensional image review, manipulation, analysis and therapy planning capabilities that support image management display needs in the medical environment from multiple locations within and outside the hospital.

Diagnostic Review Workstations - Assists medical professionals including but not limited to radiologists, surgeons, oncologists, neurologists, and cardiologists in conducting primary diagnostic review and planning through the flexible and interactive manipulation of multi-modality softcopy images.

Two and three-dimensional image coregistration (fusion) and segmentation of multiple imaging modality data including but not limited to functional MRI, PET, SPECT, and CT for user-selected regions of interest taken at different time points or generated using different scanning protocols.

Detailed measurement and reporting features assist clinicians in assessing and documenting changes in regions of interest such as pathologies (e.g., tumors, abscesses, AVMs), or other anatomical structures. The software can help track changes in morphology, functional activity, or other responses that may occur as a result of treatment therapy or disease progression.

Prescription Use [X] AND/OR Over-The-Counter Use [ ]
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C. Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053301