K040468

510 (k) Summary

Submitter:	Cedara Software Corp.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa.
Telephone:	(905) 672-2100.
Date:	February 2004.
Trade Names:	Cedara I-SoftView; Cedara I-ReadMammo
Common Name:	PACS medical imaging software
Classification Name:	Picture archiving and communications system.
Cleared Devices:	Cedara Software Corp., Cedara I SoftView, 510(k) No. K022881.
Device Description:	Cedara I-ReadMammo is medical image review workstation software that is comprised of features that are previously cleared in Cedara I-SoftView. The differences lie mainly in workflow and user interface that make mammography image viewing more convenient for the user. The product consists of features that allow the qualified medical professional to view patient medical images with the desired viewing protocol and workflow in order to optimize the efficient use of their time. Additionally, as with all Cedara I-SoftView offerings, measurements that are commonly required for diagnosis and surgical planning are available to the user.

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.

Productivity-Enhancing Second Console Workstations – Workstations designed to perform automated, routine tasks such as image review, printing and archiving as well as post processing capabilities that enable special services for referring physicians.

Diagnostic Review Workstations - Workstations designed to assist radiologists and surgeons in conducting primary diagnostic review and planning through flexible and interactive manipulation of multi-modality softcopy images including the use of prosthetic template overlays, and including mammography.

Physician's Review Workstations - Workstations designed to give easy and economic access to multi-modality softcopy images in multiple locations within and outside the hospital. (e.g. teleconferencing, teleradiology etc.)

Lossy compressed mammographic images must not be used for primary diagnostic interpretation unless approved for use in digital mammography. Display monitors used for primary diagnostic interpretation of mammographic images must be approved for use in digital mammography."

Comparison to Previously Cleared Device:	The intended use and technological characteristics of Cedara I-ReadMammo Workstation software are substantially equivalent, in the opinion of Cedara Software Corp. to those of the previously cleared device 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

APR 2 3 2004

Ms. Carol Nakagawa
Manager of Regulatory Affairs
Cedara Software Corp.
6509 Airport Road
Mississauga
Ontario, L4V 1S7
CANADA

Re: K040468
Trade/Device Name: Cedara I-SoftView
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: April 6, 2004
Received: April 7, 2004

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 (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

Indications for Use Statement

510(k) Number K040468

Device Name Cedara I-SoftView

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.

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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)

David B. Lynn

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040468