B. Administrative Information

1. 510(k) Summary

OCT 2 2 2002

Submitter:	Cedara Software Corporation
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa.
Telephone:	(905) 672-2100.
Date:	August 29, 2002.
Trade Names:	Cedara I-SoftView™; Cedara Orthopedic Tool Set; Cedara I-SoftView with Orthopedic Module
Common Name:	Medical Image processing software.
Classification Name:	Picture archiving and communications system.
Predicate Devices:	Sectra IDS5 image Display System 510(k) No. K002936; Agfa ADC Compact Plus 510(k) No. K013138; ISG Medical Imaging Family of Workstations, 510(k) No. K941933.
Device Description:	The Cedara Orthopedic tool set is a new option available in the Cedara I-SoftView product which is a line extension of Cedara's medical image processing workstation product, "Medical Imaging Family of Workstations". The Cedara Orthopedic tool set is a software accessory that will be typically used for orthopedic applications and consists of features that allow the qualified medical professional to make measurements that are commonly required when doing orthopedic surgical planning. In addition to circle, line and angle measurements, the physician can also display electronic implant templates that can aid in implant size and positioning determination prior to surgery.

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. This includes the use of prosthetic template overlays"

"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.)"

Comparison to Predicate:	The intended use and technological characteristics of Cedara I-SoftView™ software are substantially equivalent, in the opinion of Cedara Software Corporation 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

OCT 22 2002

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

Re: K022881
Trade/Device Name: Cedara I-Soft View™
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: August 29, 2002
Received: August 30, 2002

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 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 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:

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" (21 CFR Part 807.97). 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

Indication for Use Form

510(k) Number (if known): K022881

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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K022881