K081469

JUN 12 2008

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared

21 May 2008

Submitter's Information

Sectra Imtec AB
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Trade Name, Common Name, Classification

Trade Name:	Sectra Workstation
Software version:	IDS7 11.3 IDS5 11.1 P2
Common Name:	Picture Archiving and Communications System
Classification Name:	Image Processing System (LLZ) (21 CFR § 892.2050)

Predicate Device

Applicant:	Sectra Imtec AB
510(k) Number:	K063093
Device:	Sectra Workstation

Device Description

The Sectra Workstation is mainly a software product. It is used for visualization and processing of digital medical images. The Sectra Workstation is used as a client together with a Sectra provided server (Sectra PACS Core, Class I Exempt). The system runs on PCs under the Windows operating systems. Most notably two or more monitors are used.

The Sectra Workstation is a family of devices, including several workstations or types of workstations (see Table 1).

Workstation Type	Description
IDS5/dx.net	A diagnostics workstation. It contains tools for assisting the radiologist in making a diagnosis.
IDS5/mx.net	A workstation specifically designed to handle the mammography screening workflow. It has all functionality as an IDS5/dx.net but with additional features to enhance the mammography screening workflow.
IDS5/qa.net	The quality assurance workstation in the Sectra Workstation family. Mainly used by the technologists to prepare the images for the reviewing radiologist.
IDS5/mqa.net	The quality assurance workstation to be used by a mammography technician to prepare images for the reviewing radiologist.
IDS5/cl.net	Used by the clinicians within the hospital to view the radiology images and to read the radiology report.
IDS5/web	A slim version of the Sectra Workstation that can be used by remote clinics to view images and radiology reports.
IDS5/doc	A limited workstation that is used to scan radiology requests.
IDS5/send	A teleradiology workstation that is used to send examinations to teleradiology destinations.
IDS7/dx	A diagnostics workstation, based on the .NET architecture. It contains tools for assisting the radiologist in making a diagnosis.
IDS7/cl	A clinician's workstation, based on the .NET architecture. Used by the clinicians within the hospital to view the radiology images and to read the radiology report.

Table 1 Sectra Workstation types.

To handle specific user needs it is also possible to activate Sectra developed add-ons for the Sectra Workstation. An add-on is thus an additional feature set that can be used on the workstation. Some features are add-ons on Sectra Workstation IDS5 but are included as ordinary features for IDS7 (see Table 2 for examples).

Add-on	Sectra Workstation IDS5	Sectra Workstation IDS7
Volume rendering (3D)	X	X
Clinical Application Interface slots (2 additional)	X	
Dual monitor support	X	Included in IDS7 by default.
Multiframe support	X	Included in IDS7 by default.
Image cache	X	Included in IDS7 by default.
DICOM print support	X	
Image scanner support	X	
Basic document scanner support	X	
Demonstration scheduling	X	
Nuclear medicine image controls	X	
Patient CD	X	
Teleradiology	X	
WISE/doc	X	

Table 2 Examples of add-ons for Sectra Workstation.

Indications for Use

The Sectra Workstation is intended for the manipulation and displaying of medical images, including mammograms. It can show images from different modalities and interfaces to various image storage and printing devices using DICOM or similar interface standards.

Device options make possible mammography reading, telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

Lossy compressed mammographic images are not intended for diagnostic review. Mammographic images should only be viewed with a monitor approved by FDA for viewing mammographic images. For primary diagnosis, post process DICOM "for presentation" images must be used.

Typical users of this system are trained professionals, including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

Technological Characteristics

The Sectra Workstation runs under the Windows 2000 Professional[1], Windows XP Professional, and Windows Vista Business[2] operating systems for PCs (as a minimum and depending upon system configuration)[3]. The requirements on hardware are quite ordinary for a system used for displaying images. Most notably up to four monitors can be used.

Performance Data

The subject device is developed according to ISO 9001:2000 and complies with ACR/NEMA Digital Imaging Communications in Medicine version 3.0.

Conclusion

Similar to the predicate device, the Sectra Workstation does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. The device and the predicate device share the same certification or conformance to performance standards and both function as Image Processing System (LLZ). Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

Based on the information supplied in this Special 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

[1] Sectra Workstation IDS7 is not supported on Microsoft Windows 2000 Professional.
[2] Windows Vista is supported for IDS7 only.
[3] Windows NT is supported for IDS5/web.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2008

Sectra Imtec AB
% Mr. Carl Alletto
Official Correspondent
OTech, Inc.
1600 Manchester Way
CORINTH TX 76210

Re: K081469
Trade/Device Name: Sectra Workstation by Sectra Imtec AB
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: May 21, 2008
Received: May 27, 2008

Dear Mr. Alletto:

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 Center for Devices and Radiological Health's (CDRH's) 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" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 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

510(k) Number: **K081469**

Device Name: Sectra Workstation by Sectra Imtec AB

Indications For Use:

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Prescription Use ___X___ AND/OR Over -The-Counter Use _____

(Per 21 CFR 801.109) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K081469