OCT - 2 2003

Date: May 16, 2003

Sectra Document Number: 3-03.1020-1.0

K031590

510(k) Summary of Safety & Effectiveness

(as required by 21 CFR 807.92c)

Date Prepared:

May 16, 2003

Submitter's Information:

Sectra Imtec AB
Teknikringen 20
SE-583 30 Linköping
Sweden
Phone: +1 46 13 23 52 00
Fax: +1 46 13 21 21 85

Trade Name, Common Name, Classification:

Trade name:	Sectra Orthopedic Package
Common Names:	Picture Archiving and Communications System
Classification Name:	Image Processing System (LLZ) (21 CFR § 892.2050)

Predicate Device:

Applicant:	Sectra Imtec AB
510(k) Number:	K002936
Device:	Sectra IDS5 Radiology Workstation

Device Description:

Sectra Orthopedic Package is intended to assist orthopedic surgeons when doing preoperative planning and post-operative follow-up. The device has functionality for overlaying prosthesis templates on radiological images, tools for repositioning the templates, and tools for measurements in the images.

More specifically the Sectra Orthopedic Package shall: (1) assist the orthopedic surgeons in choosing which implants to use, (2) assist the orthopedic surgeons in choosing were to place cut lines etc., and (3) assist the orthopedic surgeons in following-up of surgical procedures.

Date: May 16, 2003 K031590 Sectra Document Number: 3-03.1020-1.0

Indications for Use:

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

The device assists orthopedic surgeons when doing preoperative planning and post-operative follow-up.

Typical users of this system are trained professionals, for example orthopedic surgeons, physicians, and radiologists.

Technological Characteristics:

The Sectra Orthopedic Package will run on the Windows 2000, and Windows XP operating systems for PCs (as a minimum and depending upon system configuration).

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 Orthopedic Package 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 an orthopedic surgeons 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 Picture Archiving and Communications Systems. 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 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

Peter Andersson
Regulatory Affairs Officer
Sectra Imtec AB
Teknikringen 20
SE-58330 Linköping
Sweden

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2003

Sectra Imtec AB
% Mr. Carl Alletto
OTech, Inc.
1100 Lakeview Blvd.
DENTON TX 76208

Re: K031590
Trade/Device Name: Sectra Orthopedic Package
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communication system
Regulatory Class: II
Product Code: 90 LLZ
Dated: September 5, 2003
Received: September 9, 2003

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 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

510(k) Number: K031590

Device Name: Sectra Orthopedic Package

Indications For Use:

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

The device assists orthopedic surgeons when doing preoperative planning and post-operative follow-up.

Typical users of this system are trained professionals, for example orthopedic surgeons, physicians, and radiologists.

(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 A. Lyerman

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K031590

(Optional Format 1-2-96)