JUN 26 1997

Department of Health and Human Services
Center for Devices and Radiological Health
Office of Device Evaluation
Pre-Market Notification Section

17 April 1997
K97145/

SECTRA Doc. no: 3-97.434-2.0

510(k) summary of safety and effectiveness information for the SECTRA-Imtec WISE Image Management System

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

WISE will be used for management of radiological images. The typical users are trained medical professionals at a radiology department.

The undersigned certifies that the 510(k) Pre-Market Notification for the above referenced product contains adequate information and data to enable CDRH to determine substantial equivalence to SECTRA-Imtec ImageServer 2000 (K963395). This information and data is summarised as follows:

1. WISE is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.

2. WISE has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

3. WISE User's Guides contains comprehensive and extensive information on how to operate the system to ensure a safe and effective use.

4. The submission contains the results of an hazard analysis.

Peter Andersson
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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1997

Sectra-Imtec AB
c/o Herman Oosterwijki
President
Otech Inc.
6741 Grant Lane
Plano, TX 75024

Re: K971451
Wise Image Management System
Date: April 17, 1997
Received: April 21, 1997
Regulatory class: Unclassified
Procode: 90 LMB

Dear Mr. Oosterwijk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591 for Radiology devices, or 594-4613 for Ear, Nose and Throat devices. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K971451

Device Name: WISE Image Management System

Indications For Use:

The SECTRA AB, WISE Image Management System device is intended for the management and displaying of x-ray images, other radiological objects, and information.

It can manage images from different modalities, single and multiple file servers, and interfaces to various Radiological Information Systems (RIS), image storage and printing devices using DICOM or similar interface standards.

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

(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)

(Optional Format 1-2-96)

David C. Segman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K971451