

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

21 March 1997

K971368

SECTRA Doc. no: 3-97.202-1.0

JUN 26 1997

510(k) summary of safety and effectiveness information for the SECTRA-Imtec
IDS4 Image Display System series

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

The IDS4 series will be used for displaying and handling 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 TRS 2000 (K961983). This information and data is summarised as follows:

1. The IDS4 series is subject to and in compliance with the Federal Performance Standards, defined in 21 CFR, part 1000.
2. The IDS4 series has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.
3. The IDS4 series 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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Linköping, Sweden
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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 1997

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

Re: K971368
IDS4 Image Display System Series
Dated: April 9, 1997
Received: April 14, 1997
Regulatory class: Unclassified
Procode: 90 LLZ

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: K971368

Device Name: IDS4 (Image Display System), by SECTRA-Imtec AB

Indications For Use:

The SECTRA IDS4 device is intended for the manipulation and displaying of x-ray images. 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 telecommunications; fast demonstration; prosthesis CAD; 3-D and angiography, etc.; and teleconferencing.

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 (Per 21 CFR 801.109)

OR

Over -The-Counter Use

(Optional Format 1-2-96)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971368