JUN 30 1999

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

K991282

510(k) Summary of Safety and Effectiveness

for Seiko Instruments, ColorPoint™ 1700 Medical Imagers and Video Capture Box (VCX) systems

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

Date Prepared:

April 7, 1999

Submitter's Information:

Seiko Instruments Inc.
Print System Division
8, Nakase 1-chome
Mihama-ku Chiba-shi
Chiba 261-8507
Japan

Trade Name, Common Name, Classification:

Trade Name:	Seiko Instruments, ColorPoint™ 1720 Medical Imagers and Video Capture Box CX-1000 series
Common Name:	Medical Imager & Video Capture
Device Classification Name:	Camera, Multiformat

Predicate Device:

Manufacturer:	Seiko Instruments Inc.
Device:	ColorPoint™ Model 820 Medical Imager
510(k) Number:	K971760
Date Received:	05/12/97
Decision Date:	10/01/97
Decision:	Substantially Equivalent

Panel Code device reviewed by: Radiology
Panel Code device classified by: Radiology

Product Code:	LMC
Classification:	Class II

Device Description:

The Seiko ColorPoint™ Medical Imager and Video Capture systems are designed for medical imaging applications printing color or monochrome images on paper and or film media.

Indications for Use:

The Seiko ColorPoint™ model 1700 medical imager & Video Capture Box systems are indicated for converting the electronic signals from medical imaging modalities into hard copy suitable for diagnosis and record keeping.

Technological Characteristics:

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being printed.

Conclusion:

The 510(k) Pre-Market Notification for the above referenced device contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to Seiko Instruments Inc. ColorPoint™ Model 820 Medical Imager K971760.

1. The ColorPoint™ system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey.

3. The submission contains the results of a hazard analysis. All potential hazards have been classified as MINOR.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 30 1999

Seiko Instruments USA., Inc.
c/o Herman Oosterwjick
Division of Otech, Inc.
2001 East Oakshores Drive
Crossroads, TX 76227

RE: K991282
Trade Name: Colorpoint 1720 Medical Imagers and Video Capture Box CX-1000 Series
Date: March 31, 1999
Received: April 14, 1999
Classification: II
21 CFR 892.2040
Product Code: 90 LMC

Dear Mr. Oosterwjick:

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 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). 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 Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS 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) 594-4613. 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/dsma/dsmamain.html".

Sincerely yours,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

(Indications for Use Form)

510(k) Number: K991282

Device Name:

Seiko Instruments, ColorPoint™ 1720 Medical Imagers and Video Capture Box CX-1000 series

Indications for Use:

The Seiko ColorPoint™ model 1700 medical imager & Video Capture Box systems are indicated for converting the electronic signals from medical imaging modalities into hard copy suitable for diagnosis and record keeping.

(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)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K991282