DATA-RAY CORPORATION

12300 Pecos Street
Westminster, CO 80234
Phone: 303-451-1300

DEC 15 1998

K983392

510(k) Notification

PREMARKET NOTIFICATION SUMMARY

Manufacturer: Data Ray Corporation
12300 Pecos Street
Westminster, CO 80234

Contact Information: Greg Roberts, Compliance Engineer
Phone: 303-451-1300
Fax: 303-451-1143

Classification Name: Display, cathode ray tube, image communication accessory/device

Common Name: Monitor, monochrome monitor, display, high-resolution monitor, and the like.

Manufacturer's Name: DR11021 Medical Imaging Monitor

Classification Number: 90 LMD

Substantially Equivilant To: Barco NV/Display Systems, Barco MGD 521 5 Megapixel Diagnostic Display (K980541), Barco MWD 321 Medical Workstation Display (K972701), Sony Medical Systems Division, Sony PGM-1001MD Trinitron Color Graphic Monitor (K970999), Aurora Technology, Aurora Diagnostic Workstation (K962589), Accuimage Inc., Accuimage Inc. Image Display Processor (K961023), GE Medical Systems, GE Advantage Windows Review Workstation (K960613), and others.

Device Description: The DR11021 Medical Imaging Monitor is a diagnostic display used in film-less radiology applications.

Intended Use: The Data Ray Corporation's DR11021 Medical Imaging Monitor is intended to be used by radiologists/trained practitioners to examine digitized x-ray images for the purpose of medical analysis.

Technological Characteristics: The Data Ray Corporation DR11021 Medical Imaging Monitor is a high resolution monitor with the electronic capability necessary for displaying high resolution medical images for the purpose of evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 1998

Greg Roberts
Compliance Engineer
Data-Ray Corporation
12300 Pecos Street
Westiminster, CO 80234

Re: K983392
DR11021 Medical Imaging Monitor
Dated: September 18, 1998
Received: September 25, 1998
Regulatory class: II
21 CFR 892.2050/Procode: 90 LLZ

Dear Mr. Roberts:

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

510(k) NUMBER (IF KNOWN) : ~~K9883392~~ K983392

DEVICE NAME: DATA RAY CORPORATION DR11021 MEDICAL IMAGING MONITOR

INDICATIONS FOR USE :

The Data Ray Corporation DR11021 Medical Imaging Monitor is used in filmless radiology systems to display digitized x-ray images. These digitized x-ray images are viewed by trained medical providers for the purpose of diagnosing and/or treating illnesses in human beings.

DO NOT WRITE BELOW THIS LINE

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter-Use ____ (Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K983392