K970999

510(k) Summary
for
Sony PGM-100P1MD Trinitron® Color Graphic Monitor

MAY 20 1997

1. **Applicant:**

Sony Medical Systems Division
Sony Electronics Inc.
3 Paragon Drive
Montvale, NJ 07645

Contact Person: Anthony John Kefalos
Telephone: 201-358-4330

Date Prepared: March 18, 1997

2. **Device Name**

Proprietary Name: Sony PGM-100P1MD Trinitron® Color Graphic Monitor

Common/Usual Name: Color Graphic Monitor

Classification Name: Accessory to Medical Imaging, Monitoring and Diagnostic Devices

Classification Status: Class II

3. **Predicate Devices**

- Sony Trinitron Color Video Monitor PVM-1343MD
  Sony Medical Systems Division
  K885042

- Electrohome M1544/1744 High Resolution Monochrome Monitors
  Electrohome Limited

- Siemens Sirecust 1481T Digital Telemetry System (includes the Sony Trinitron® Character Display CPD-1304 as the monitor component)
  Siemens Medical Electronics, Inc.
  K900319

4. Device Description

The Sony PGM-100P1MD Trinitron® Color Graphic Monitor is a general purpose computer monitor which has been modified for use in medical settings for patient monitoring applications. It will display images received from a computer system and is designed for use with PC-compatible computers.

5. Intended Use

The Sony PGM-100P1MD Trinitron® Color Graphic Monitor is intended for use in patient monitoring applications to display multi-parameter data in graphic format.

6. Technological Characteristics

The Sony PGM-100P1MD Trinitron® Color Graphic Monitor is intended as an addition to the Sony video monitor product line and has the same general purposes and function as the predicate devices identified above. All of the devices accept standard video signals produced by a wide range of equipment. The primary difference between the Sony PGM-100P1MD and the predicate devices is the higher resolution that it provides for use in graphical display.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Cynthia A. Sinclair
Sony Medical Systems
C/O Medical Device Consult, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K970999
Sony PGM-100P1MD Trinitron® Color Graphic Monitor
Dated: March 18, 1997
Received: March 19, 1997
Regulatory class: II
21 CFR 892.1750/Procode: 90 JAK

Dear Ms. Sinclair:

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 (if known): K970999

Device Name: Sony PGM-100P1MD Trinitron® Color Graphic Monitor

Indications For Use:

The Sony PGM-100P1MD Trinitron® Color Graphic Monitor is intended for use in patient monitoring applications ~~to display multi-parameter data in graphic format~~. The Sony PGM-100P1MD can be used in hospital settings such as the intensive care unit, central station, and nurse station. Applications include the display of data from electrocardiographs, blood pressure and pulse measurement systems, and computed tomography and other imaging systems.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

David C. Dejarnette

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K970999

Prescription Use X OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)