

SEP 17 1998

K982171

## 510(k) Summary

### Hamamatsu PET Scanner Model SHR-22000

Common/Classification Name: PET Scanner, 21 CFR 892.1200

Hamamatsu Photonics, K.K.  
325-6, Sunayama-cho  
Hamamatsu City 430  
JAPAN

Contact: Keith Kobayashi, Prepared: May 18, 1998

#### A. LEGALLY MARKETED PREDICATE DEVICES

The **Hamamatsu PET Scanner Model SHR-22000** is substantially equivalent to the Siemens ECAT Exact HR PET scanner (K962797).

#### B. DEVICE DESCRIPTION

The **Hamamatsu PET Scanner Model SHR-22000** is similar to previous PET scanners marketed by other companies, but it represents an increase in performance over other PET Scanners through improved resolution. The system was developed in a joint venture with Hitachi Medical Corporation (HMC). HMC provided the imaging workstation, patient table, and user interface, adapted from its nuclear medicine imaging workstation.

The **SHR-22000 PET Scanner** system consists of five main sub-systems: the main gantry with the detector arrays, the signal processing unit, the data acquisition unit, the patient table and positioning sub-system, and the imaging workstation and user interface.

**Model SHR-22000** has almost 22000 scintillator segments in its detector arrays, providing very fine resolution. The gantry also has a  $^{68}\text{Ge}$ - $^{68}\text{Ga}$  source mounted in a stainless steel rod for calibration.

#### C. INTENDED USE

The Hamamatsu PET Scanner Model SHR-22000 is indicated for the imaging of the distribution in the body of physiological tracer molecules labeled with positron-emitting isotopes. Such images are

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particularly useful in the assessment of brain function.

#### **D. SUBSTANTIAL EQUIVALENCE SUMMARY**

The **Hamamatsu PET Scanner Model SHR-22000** is a medical device, and it has similar indications for use as the legally marketed predicate device. The two devices have the same intended use.

The **Hamamatsu PET Scanner Model SHR-22000** has the same technological characteristics as the predicate devices.

This premarket notification describes most of the characteristics of the **Hamamatsu PET Scanner Model SHR-22000** in sufficient detail to assure substantial equivalence. For a few characteristics, performance data is provided to assure equivalence.

#### **E. TECHNOLOGICAL CHARACTERISTICS**

The **Hamamatsu PET Scanner Model SHR-22000** has the "same technological characteristics" as the predicate devices. Both employ coincidence detection from thousands of scintillator segments to reconstruct cross-sectional medical images using standard image reconstruction algorithms. The image processing algorithms in the workstation manipulate and display medical images on the workstation monitor.

#### **F. TESTING**

The **Hamamatsu PET Scanner Model SHR-22000** was tested for compliance with the Japanese Industry Standard on electrical safety. Imaging performance tests were carried out to assure equivalence of image characteristics with the predicate device.

#### **G. CONCLUSIONS**

The 510(k) decision algorithm brings us to a determination of Substantial Equivalence, as defined in the Federal Food, Drug, and Cosmetic Act.



SEP 17 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850Hamamatsu Photonics, K.K.  
T. Whit Athey, Ph.D.  
c/o C.L. McIntosh & Associates  
12300 Twinbrook Parkway  
Suite 625  
Rockville, Maryland 20852Re: K982171  
Hamamatsu PET Imaging System Model  
SHR-22000  
Dated: June 18, 1998  
Received: June 19, 1998  
Regulatory class: II  
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Athey:

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 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,

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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): \_\_\_\_\_

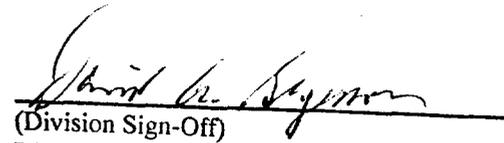
Device Name: Hamamatsu PET Scanner Model SHR-22000

Indications For Use:

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K982171

Prescription Use              
(Per 21 CFR 801.109)

OR

Over-The-Counter Use