K992335

OCT 7 1999

PICKER INTERNATIONAL 510(k) NOTICE

BEACON P SYSTEM

E: SUMMARY OF SAFETY AND EFFECTIVENESS

This is a summary of the information submitted by Picker International, Inc. to the Office of Device Evaluation (DRAERD) of the FDA as required by the Federal Food, Drug, and Cosmetic Act as amended on November 18, 1990 in section 807.92(c) for the Beacon P system.

The Beacon P system is a new option for non-uniform attenuation correction on the Axis or Irix gamma camera systems. This device is intended to be used for diagnostic imaging of organs and lesions. There is no change of intended use from that of the predicate device. This device includes adding hardware and software to a gamma camera system.

Functional specifications and operator's instructions (preliminary) are included in the attachments. Final documentation will be provided with productions units.

The Beacon P system is substantially equivalent to legally marketed devices. The system will be operated by trained health care professionals who are responsible for Nuclear Medicine diagnostic examinations. The Beacon P system will be certified to electrical safety standards (IEC-601 or UL-544) by a third party organization prior to commercial distribution of the device. Labeling (Product Bulletin and Operator's Manual) will be provided to the user of the equipment.

Laboratory tests will be run to validate the image quality performance of the system. The product will perform in accordance with the development specifications. A matrix was enclosed comparing the Beacon P to a predicate device and therefore we concluded that it is substantially equivalent to that legally marketed predicate device.

Picker has reviewed all known information and performed an investigation as to the causes of safety and effectiveness concerning the Beacon P. In addition, all information contained in this 510(k) Notice is accurate and complete.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 7 1999

Ronald J. Martone
Manager, Regulatory Affairs
Picker International
Nuclear Medicine Division
595 Miner Road
Highland Heights, Ohio 44143

Re: K992335
Beacon P, Model 211059
Dated: July 5, 1999
Received: July 13, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Martone:

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): K992335

Device Name: Beacon P

Indications For Use:

The Beacon P option is intended to be used specifically for Attenuation Correction of Coincidence Imaging of positron emitters performed only on Axis or Irix gamma camera systems.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992335

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)