4/16/95

PICKER INTERNATIONAL 510(k) NOTICE K983948

BEACON S 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 system.

The Beacon 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 system is substantially equivalent to legally marketed devices. Trained health care professionals who are responsible for Nuclear Medicine diagnostic examinations will operate the system. The Beacon system will be certified to electrical safety standards (IEC-601 or UL-544) by a third party organization prior to use on human patients. Labeling (Product Bulletin and Operator's Guide) will be provided to the user of the equipment.

This device will be developed to our quality system which includes design controls. The quality standard procedure OI 2300 "Program Planning and Control System" defines how an engineering project goes from concept to closure. This procedure complies with the FDA-QSR regulation and the ISO-9001 standard.

Picker has reviewed all known information and performed an investigation as to the causes of safety and effectiveness concerning the Beacon. 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

APR 16 1999

Norman J. Yager
Manager, QA/Regulatory
Picker International, Inc.
Nuclear Medicine Division
595 Miner Road
Highland Heights, Ohio 44143

Re: K983948
Beacon-S Model 211060
Dated: February 26, 1999
Received: March 1, 1999
Regulatory class: II
21 CFR 892.1200/Procode: 90 KPS

Dear Mr. Yager:

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): K983948

Device Name: BEACON-S

Nuclear Medicine Device

Indication For Use: To detect or image the distribution of radionuclides in the body or organ, using the following technique(s).

	YES	NO	Energy Range (keV)
A. Planar imaging	___	X	___
B. Whole body imaging	___	X	___
C. Tomographic imaging (SPECT) for non Positron emitter	X	___	50-550
D. Positron imaging by coincidence	___	X	___
E. Positron imaging without coincidence	___	X	___
F. Other indication(s) in the device label, but not included in above list		N.A.	

(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)

for DAS

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K983948