

Picker 510(k) Notice

FV-RF

Summary of Safety and Effectiveness

This is a summary of the information submitted by Picker International, Inc. to the Office of Device Evaluation (ODE), specifically DRAERD of the FDA as required by the Federal Food, Drug, and Cosmetic Act as amended on November 18, 1990 in section 513(f)(3).

The FV-RF is a Stationary X-ray System, a device intended for radiographic/fluoroscopic examinations of various anatomical regions. This device may include signal analysis and display equipment, patient and equipment supports, components and accessories.

Preliminary functional specifications and operator's instructions are included in the Attachments "B" and "C" respectively. Final documentation will be provided with production units.

The FV-RF is substantially equivalent to legally marketed devices and is under control of health care professionals who are trained and responsible for radiographic and fluoroscopic examinations. The FV-RF will be certified to comply with Federal Diagnostic X-Ray Performance Standards. Labeling (Product Specification and Operator's Manual) will be provided to the user of the equipment.

Shimadzu adheres to FDA 21 CFR 820, 1020.30 through 32, and voluntary standards for safety and effectiveness (UL 187) all of which mandate that components are tested to minimize hazards (electrical, mechanical, and radiation). In addition, the system is designed to conform to IEC 601-1.

Effectiveness is established by Shimadzu's evaluation throughout all phases of the FV-RF development. The product will perform in accordance with the development specifications. The FV-RF represents the current state-of-the-art technology, therefore, is equivalent to legally marketed devices.

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



DEC 11 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850Michael J. Hayes
Senior Product Review Engineer
Picker International, Inc.
595 Milner Road
Cleveland, Ohio 44143Re: K984111
FV-RF (Radiographic/Fluoroscopic System)
Dated: November 16, 1998
Received: November 17, 1998
Regulatory class: II
21 CFR 892.1680/Procode: 90 KPR

Dear Mr. Hayes:

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

FV-RF Number (if known): K_____

Device Name: FV-RF

Indications for Use: Routine Radiographic/Fluoroscopic examinations of the entire human anatomy, gastrointestinal tract, interventional capabilities, and organ examination.

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

David G. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K984111

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____
(Optional Format 1-2-96)