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K980918

JPACS SUBSTANTIAL EQUIVALENCE SUMMARY K980918, page 1 OF 3

The following information is being submitted in accordance with 21 CFR 807.92(a) and in the order specified in that section.

(1) The submitter's name, address, telephone number, a contact person, and the date the summary was prepared;

Submitter: Picker International, Inc.
595 miner Road
Highland Heights, Ohio 44143
(440)473-3000

Contact: Robert L. Turocy
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143
(440) 473-3528

Date of Summary: March 26, 1998

(2) The name of the device, including the trade name or proprietary name if applicable, the common or usual name, and the classification name, if known;

Device Name
(Proprietary Name): JPACS

Classification Name: Picture Archiving & Communication System
Common Name: Picture Archiving & Communication System

The FDA has classified the JPACS as a Class II device, "Unclassified" Procode 90 LLZ based on recommendation of the Radiology Devices Panel.

(3) An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from Class III to Class II or I the predicate) or a device which has been found to be substantially equivalent through the 510(k) Premarket Notification process.

Picker claims equivalence to the legally marketed device identified as the Medisurf manufactured by Algotec Systems Ltd. granted marketing permission in Document Control Number K971347.

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(4) A description of the device that is the subject of the Premarket Notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device such as device design, material used, and physical properties;

The JPACS radiology suite is intended to provide access to clinical reports and images via computer networks. It is also intended to provide short, medium and long range storage of clinical images from any authorized workstation within an intranet or over the Internet. The full feature imaging suite can be used for in-house image distribution, on-call teleradiology, and advance visual display features. The JPACS radiology suite also includes functionality for generation and distribution of clinical reports. Picker adheres to FDA 21 CFR 820 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. The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, and mode of operation are equivalent. External communication uses DICOM V. 3.0 NEMA Standards Publication Parts PS3.1 through PS3.13, dated 1996.

(5) A statement of the intended use of the device that is subject of the Premarket Notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or will mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled; and

Intended Use Statement: The JPACS radiology suite is intended to provide access to clinical reports and images via computer networks. It is also intended to provide short, medium and long range storage of clinical images from any authorized workstation within an intranet or over the Internet. The full feature imaging suite can be used for in-house image distribution, on-call teleradiology, and advance visual display features. The JPACS radiology suite also includes functionality for generation and distribution of clinical reports.

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(6) If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.

Claims: The JPACS is a comparable type and substantially equivalent to legally marketed devices. The intended use of the JPACS is the same as legally marketed device Medisurf manufactured by Algotec Systems Ltd. granted marketing permission and no new questions of safety or effectiveness are raised with the JPACS. The subject device has the same technological characteristics as a legally marketed predicate device. Specifically, the features, specifications, materials, mode of operation are equivalent.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Robert L. Turocy
Regulatory Affairs & Compliance Manager
Picker International, Inc.
595 Miner Road
Highland Heights, Ohio 44143

Re: K980918
JPACS
Dated: March 6, 1998
Received: March 11, 1998
Regulatory class: Unclassified
Procode: 90 LMD

Dear Mr. Turocy:

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

510(K) Number (if known): K98 0918

Device Name: JPACS

Indications for Use:

The JPACS radiology suite provides access to clinical reports and images via computer networks. Given the following information objects, the JPACS radiology suite may be used on any part of the human anatomy: CR, CT, MR, XA, SC, US, NM, PET, and RT. The suite also provides short, medium, and long term storage of these clinical images from any authorized workstation within an intranet or over the Internet. The full feature imaging suite can be used for in-house image distribution, on-call teleradiology, and advance visual display features. The JPACS radiology suite also includes functionality for generation and distribution of clinical reports.

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

David A. Segerson

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K980918

Prescription Use
(Per 21 CFR 801.109)

OR

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