

NOV 19 1998

Picker 510(k) Notice**FACTS****SUBSTANTIAL EQUIVALENCE SUMMARY**

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: June 5, 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): FACTS

Classification Name: Computed Tomography X-Ray System
and Solid State X-Ray Imaging Device

Common Name: Computed Tomography X-Ray System
and Solid State X-Ray Imaging Device

The FDA has classified the FACTS as a combination of a CT System as Class II in 21 CFR 892.1750 (ProCode 90JAK) plus the FACTS Monoblock Diagnostic Source Assembly as Class II in 21 CFR 892.1610 (Product Code 90 IZX/90 ITY/90IZO) plus a SSXI Class II in 892.1660 (Product Code 90MQB) based on the recommendations of the Radiology Devices Panel.

Continued FACTS SUBSTANTIAL EQUIVALENCE SUMMARY

(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 substantial equivalence of the FACTS to the combination of legally marketed devices with a SSXI. The intended use of the FACTS is the same as legally marketed device PQ2000+ CT System granted marketing permission in K955268 combined with a C-Arm including the DynaRad Diagnostic Source Assembly cleared in K981267 and a SSXI subject of this 510(k) manufactured by Varian for Picker that is equivalent to the image intensifier of the Orbitor cleared in K800639. No new questions of safety or effectiveness are raised with the combination and introduction of this device.

(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 FACTS X-Ray System, is a device intended to produce cross-sectional images of the human body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The solid state x-ray imager is a device intended to be used to visualize anatomical structures by using a flat panel to convert x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. For additional information about the FACTS, please refer to the preliminary Promotional Literature, Product Specification in Attachment "B" and the preliminary Operator's Manual in Attachment "C."

Picker FACTS is designed and manufactured in accordance with FDA 21CFR 820, 1020.30 through 1020.33, 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 devices. Specifically, the features, specifications, materials, and mode of operation are equivalent. The FACTS is year 2000 ready.

Continued FACTS SUBSTANTIAL EQUIVALENCE SUMMARY

(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

The FACTS is intended to produce routine cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles of the entire human body. In addition, this device's fluoroscopic mode is intended to be used in CT interventional procedures and allows some minimally invasive surgical procedures to be implemented with the CT system. Procedures possible with this equipment include tumor biopsies, abscess drainage's, bone intervention, visceral, neck trauma evaluation and catheter placement for organ assessment.

(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 FACTS is a comparable type and substantially equivalent to legally marketed devices. The intended use of the The FACTS X-Ray System, is a device intended to produce cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles. The solid state x-ray imager is a device intended to be used to visualize anatomical structures by using a flat panel to convert x-radiation into a visible image. This generic type of device may include signal analysis and display equipment, patient and equipment supports, component parts, and accessories. Specifically, the features, specifications, materials, mode of operation are equivalent.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

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Regulatory Affairs & Compliance Manager
Picker International, Inc.
World Headquarters
595 Miner Road
CLEVELAND OH 44143

AUG 23 2013

Re: K982010

Trade/Device Name: FACTS (fluoroscopic assisted computed tomography system)
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK, OWB, and JAA
Dated: September 18, 1998
Received: September 21, 1998

Dear Mr. Turocy:

This letter corrects our substantially equivalent letter of November 19, 1998.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

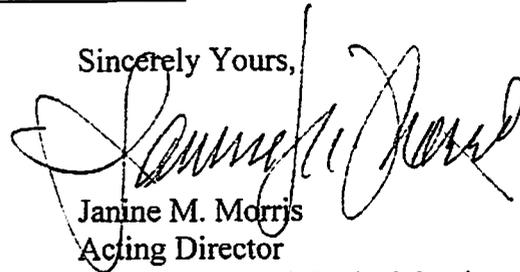
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

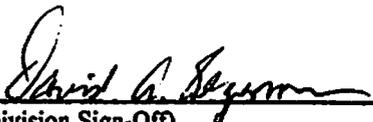
510(K) Number (if known): K98 2010

Device Name: FACTS

Indications for Use:

The FACTS is intended to produce routine cross-sectional images of the body by computer reconstruction of x-ray transmission data from the same axial plane taken at different angles of the entire human body. In addition, this device's fluoroscopic mode is intended to be used in CT interventional procedures and allows some minimally invasive surgical procedures to be implemented with the CT system. Procedures possible with this equipment include tumor biopsies, abscess drainage's, bone intervention, visceral, neck trauma evaluation and catheter placement for organ assessment.

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



(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982010

Prescription Use X
(Per 21 CFR 801.109)

OR

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