K100798

510(k) SUMMARY

OFFICIAL CONTACT: Susan Lynn Felix
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JUN 23 2010

CLASSIFICATION NAME:	Infusion Pump, FRN
COMMON NAME(S):	PET Infusion Pump
PROPRIETARY NAME:	MEDRAD Intego™ PET Infusion System
PREDICATE DEVICE(S):	MEDRAD Intego™ PET Infusion System

INTENDED USE: The MEDRAD Intego™ PET Infusion System in intended to deliver accurate doses of ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. The MEDRAD Intego™ PET Infusion System is also intended to provide effective radiation shielding to medical personnel from Fluorine-18 (^{18}F) radiation exposure during nuclear medicine diagnostic procedures.

CONTRAINDICATIONS: None known.

DEVICE DESCRIPTION: The MEDRAD Intego™ PET Infusion System is a self-contained, shielded mobile cart. ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) is stored within a shielded chamber within the body of the MEDRAD Intego™ PET Infusion System in a bulk container until the time of infusion. A multi-patient Source Administration Set (SAS) is installed within the shielded chamber at the same time a new bulk container of ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) is installed. Just prior to the infusion, the MEDRAD Intego™ PET Infusion System measures a dosage of ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) and a volume of saline flush in the dose calibrator. Once the correct radiation level is achieved, the dose of ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) / saline is injected into the patient via a disposable patient administration set (PAS).

The infusion system fulfills the following clinical needs:

a. Dispense accurate dose of ^{18}F-Fluorodeoxyglucose (^{18}F-FDG) or ^{18}F-Sodium Fluoride (^{18}F-NaF) radiopharmaceuticals and commonly used flushing solutions to patients during nuclear medicine diagnostic procedures.
b. Provide effective radiation shielding to medical personnel from Fluoride-18 (^{18}F) radiation exposure during nuclear medicine diagnostic procedures.

The MEDRAD Intego™ PET Infusion System meets the following performance requirements:

a. For a typical 15mCi infusion per patient, ^{18}F radiation exposure for medical personnel will be less than 6mRem finger dose and 0.3 mRem whole body dose.
b. Flexibility to program the required dose either by activity only or by activity per patient weight.
c. Ability to deliver ^{18}F radiopharmaceuticals within +/- 10% of the prescribed dose and within +/- 2% of the measured dose, excluding ionization chamber calibration factor.
d. Capability to retain and print infusion history and dispensing records.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

JUN 23 2010

Ms. Susan Lynn Felix
Senior Regulatory Affairs Specialist
MEDRAD, Inc.
One MEDRAD Drive
INDIANOLA PA 15051

Re: K100798
Trade/Device Name: MEDRAD Intego™ PET Infusion System for ^{18}F Fluorodeoxyglucose (FDG) or ^{18}F Sodium Fluoride (NaF)
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion pump
Regulatory Class: II
Product Code: FRN
Dated: March 19, 2010
Received: March 22, 2010

Dear Ms. Felix:

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,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100798

Device Name: MEDRAD Intego™ PET Infusion System for ^{18}F Fluorodeoxyglucose (FDG) or ^{18}F Sodium Fluoride (NaF)

Indications for Use:

The MEDRAD Intego™ PET Infusion System for ^{18}F Fluorodeoxyglucose (FDG) or ^{18}F Sodium Fluoride (NaF) is intended to deliver accurate doses of ^{18}F Fluorodeoxyglucose (FDG) or ^{18}F Sodium Fluoride (NaF) radiopharmaceuticals and commonly used flushing solutions to patients during molecular imaging (nuclear medicine) diagnostic procedures. The MEDRAD Intego™ PET Infusion System is also intended to provide effective radiation shielding to medical personnel from Fluorine-18 (^{18}F) radiation exposure during nuclear medicine diagnostic procedures.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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