K102073

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SECTION 5 - 510(K) SUMMARY

Date of Summary: September 22, 2010

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Official Contact: Cheryl Brown – QA / RA Manager

Proprietary Name:	MED-RX Transfer Set
Common Name:	Intravascular Administration Set
Classification Name:	Intravascular Administration Set, 880.5440 Intravascular Administration Set.
Class:	Class II
Product Code:	FPA
Predicate Device:	Medrad Transfer Set (K022431) Medrad Swabbable Valve Transfer Set (K031808)

Device Description

The MED-RX Transfer Set is offered in four (4) different models: 10-1227TS, 10-1300TS, 10-1305TS, and 10-1306TS. The MED-RX Transfer Set is intended to be used in the delivery of contrast media or saline from a spikeable container into a syringe. The MED-RX Transfer Sets each consist of a spike, tubing, and either a valve (swabbable or dual check) or 3-way stopcock. All sets but the 10-1306TS also have a pinch clamp. The tube is made of polyvinyl chloride (PVC) and is available in lengths from 18" – 44". The MED-RX Transfer Sets are provided sterile and are not to be resterilized.

Indications for Use

The MED-RX Transfer Set is intended to be used in the delivery of contrast media or saline from a spikeable container into a syringe.

Substantial Equivalence

The information provided in the premarket notification demonstrates that the proposed device is substantially equivalent to legally marketed devices. The proposed MED-RX Transfer Sets are substantially equivalent to the predicate Medrad Transfer Set (K022431) and Medrad Swabbable Valve Transfer Set (K031808). All devices have the same intended use to deliver contrast media or saline from a spikeable container into a syringe. All devices allow multiple filling from one reservoir up to a 6 hour time limit.

A comparison of features and principles of operation between the proposed device and predicate device is provided in Table 1 below.

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Table 1: Comparison between MED-RX Transfer Set, Medrad Transfer Set (K022431), and Medrad Swabbable Valve Transfer Set (K031808)

ATTRIBUTE	PROPOSED DEVICE – MED-RX Transfer Set	PREDICATE DEVICE – Medrad Transfer Set (K022431)	PREDICATE DEVICE – Medrad Swabbable Valve Transfer Set (K031808)
General Indications			
Indications for Use	Delivery of contrast media or saline from a spikeable container into a syringe	Same	Same
System Configuration	1 Part System – multi-fill spike system	Same	Same
Time Limit	6 hours maximum	Same	Same
Multi - fill	Yes, until reservoir is empty or time limit reached	Yes	Yes
Shelf Container	For use with one container of media only	Same	Same
Prescription	Yes	Yes	Yes
Intended Environment of Use	Hospital	Same	Same
Material Composition			
Tubing	Polyvinyl Chloride - DEHP free	PVC – medical grade	PVC – medical grade
Adhesive	Cyclohexanone and 3921 Light Cure Adhesive	Cyclohexanone and 3321 Light Cure Adhesive	Cyclohexanone and 3321 Light Cure Adhesive
Packaging and Sterilization			
Sterile	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide (EO)	Same	Same
Packaging Configuration	Medical grade peelable paper/ poly pouch	Same	Same
DIFFERENCES			
Physical Specifications			
Tubing outer diameter (OD)	0.158" – 0.168"	0.160"	0.160"
Tubing inner diameter (ID)	0.095" – 0.111"	0.110"	0.120"
Tubing length	18", 20", 31", 44"	20"	23"
Design Features			
Distal Configuration	Dual check valve *OR* 3-way stopcock *OR* swabbable luer valve	One-way stopcock	Swabbable threaded valve
Proximal Configuration	Universal spike *OR* Vented spike	Hyperal vented spike	Hyperal vented spike
Clamp	Pinch clamp (except for 10-1306)	Pinch clamp	None
Caps	Luer caps (except for 10-1306)	Luer caps	None

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Summary of Differences

There are no significant differences between the proposed MED-RX Transfer Sets and the predicate devices, Medrad Transfer Set (K022431) and Medrad Swabbable Valve Transfer Set (K031808). Similarities between the proposed device and the predicate devices include identical indications for use and duration of use. The MED-RX Transfer Sets and the Medrad Transfer Set and Medrad Swabbable Valve Transfer Set are sterile, disposable devices, packaged in peelable paper/poly pouches and sterilized using ethylene oxide.

The proposed MED-RX Transfer Sets to be offered utilize either a dual-check valve, a stopcock, or a luer compatible swabbable valve on the distal end of the set. The predicate Medrad Transfer Set has a stopcock while the predicate Medrad Swabbable Valve Transfer Set has a luer threaded swabbable valve. The dual-check valve used on the MED-RX Transfer Set is not offered on either of the predicate devices, but is a very similar component to the stopcock utilized, both of which are luer compatible, with two user-accessible ports.

Therefore, any minor differences between the proposed device and the predicate have been evaluated to have no impact on safety or effectiveness of the MED-RX Transfer Sets. Therefore the proposed device can be considered substantially equivalent to legally market devices.

Non-Clinical Test Summary

Verification of functional performance of the MED-RX Transfer Sets has been performed as per ISO 8536-4: 2007. The MED-RX Transfer Sets were subject to numerous performance tests including tensile strength, resistance to leakage under pressure and also for resistance to liquid leakage, particulate contamination, and for chemical requirements. The MED-RX Transfer Sets have successfully completed all required performance testing following the applicable guidelines of ISO 8536-4: 2007 and were tested for natural rubber latex content. Please refer to Table 2.

Table 2: Non-Clinical Test Summary

Test	Standard	Results
Particulate Contamination	ISO 8536-4: 2007	Samples met contamination index limit.
Leakage under Pressure	ISO 8536-4:2007	Pass
Liquid Leakage	ISO 8536-4:2007	Pass
Tensile Strength –Tubing/Spike	ISO 8536-4:2007	Withstand 15 N for 15 Seconds = Pass

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Test	Standard	Results
Tensile Strength – Tubing/Valve	ISO 8536-4:2007	Withstand 15 N for 15 Seconds = Pass
Demonstrate MED-RX Transfer Sets are capable of withstanding the designated test force without damage or separation.	ISO 8536-4:2007	Pass
Efficiency of the Air Filter	ISO 8536-4:2007	Pass
Flow Rate Test	ISO 8536-4:2007	Pass
Chemical Requirements	ISO 8536-4:2007 PER Clause5 & 7	Pass
Natural Rubber Latex Content	Modified Lowry Method	Device does not contain natural rubber latex

Summary of Sterilization

Each MED-RX Transfer Set is individually packaged using a medical grade peelable synthetic polymer reinforced paper with a film backing, and sterilized using ethylene oxide. Please see Table 3 for a summary.

Table 3: Sterilization Summary

Test Description	Standard	Results
Method of Validation	ANSI/AMMI/ISO 11135:1994	Validated to a Sterility Assurance Level of 1×10^{-6}
EO Sterilization Residuals	ISO 10993-7: 2008	Pass
Bacterial Endotoxins	ANSI/AAMI ST72:2002	Pass

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Summary of Biocompatibility Tests

Biocompatibility testing was successfully completed on sterile finished devices. The MED-RX Transfer Sets are classified as external communicating devices with limited indirect blood path contact. A summary of the testing completed and the relevant standards are listed in Table 4.

Table 4: Biocompatibility Test Summary

Test Description	Standard	Results
Hemolysis Assay – Extract Method	ASTM F-756-00	Product code 10-1300, 10-1305, 10-1306 and 10-1227 is considered non-hemolytic and passes the test.
Acute Systemic Injection Test	ISO 10993-11	The findings indicate that the requirements of the ISO Acute Systemic Injection Test have been met.
Materials Mediated Rabbit Pyrogen Test	USP 32:2009 <151>	Product code 10-1300, 10-1305, 10-1306 and 10-1227 was determined to be non-pyrogenic.
Intracutaneous Reactivity Test	ISO 10993-10:2002	Product code 10-1300, 10-1305, 10-1306 and 10-1227 would be considered a non-irritant.
Guinea Pig Maximization Sensitization Test (Method of Biomaterial Extracts)	ISO 10993-10:2002	Product code 10-1300, 10-1305, 10-1306 and 10-1227 did not elicit a sensitization response.
ISO MEM Elution with L-929 Mouse Fibroblast Cells (Cytotoxicity)	ISO 10993-5: 2009	Product code 10-1300, 10-1305, 10-1306 and 10-1227 are considered non-toxic.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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Re: K102073
Trade/Device Name: MED-RX Transfer Set
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FPA
Dated: October 27, 2010
Received: October 28, 2010

Dear Mr. Smith:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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SECTION 4 - INDICATIONS FOR USE

NOV - 8 2010

510(K) Number (If Known): K102073

Device Name: MED-RX Transfer Set

Indications For Use:

The **MED-RX Transfer Set** is intended to be used in the delivery of contrast media **or** saline from a spikeable container into a syringe.

Prescription Use:	✓	AND/OR	Over-the-Counter Use	N/A
(Part 21 CFR 801 Subpart D)			(21 CFR 801 Subpart C)	

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman 11/5/2010
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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