



Food and Drug Administration
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February 4, 2016

Osprey Medical, Inc.
Melanie Hess
Vice President, Regulatory Affairs
5600 Rowland Road Suite 250
Minnetonka, Minnesota 55343

Re: K153141

Trade/Device Name: DyeVert Contrast Modulation System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: December 22, 2015
Received: December 23, 2015

Dear Melanie Hess:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

Kenneth J. Cavanaugh -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

510(k) Number (if known)

TBD

Device Name

DyeVert Contrast Modulation System

Indications for Use (Describe)

The DyeVert™ Contrast Modulation System is to be used for the controlled infusion and contrast volume reduction of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/mL, Iohexol 300 or 350 mgI/mL and Iopamidol 370 mgI/mL.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

510(k) Summary As required by 21CFR 807.92(c)

510(k) Number: K153141
Date Prepared: November 02, 2015

Submitter's Name/Address: Osprey Medical
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Contact Person: Melanie Hess
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Device Information:

Trade Name/Proprietary Name: DyeVert™ Contrast Modulation System
Manufacturer: Osprey Medical, Inc.
Common Name: Injector and Syringe, Angiographic
Classification Registration: 21 CFR § 870.1650
Product Code: DXT
FDA Center/Branch: CDRH/Interventional Cardiology Devices Branch (ICDB)

Device Description:

The Osprey Medical DyeVert™ Contrast Modulation System provides a second fluid pathway that modifies the overall system resistance as experienced during the physician's manual injection and allows for excess (i.e. contrast that is not needed for diagnostic or therapeutic purposes) contrast media to be diverted into a reservoir and away from the patient while maintaining adequate image quality. Excess contrast is typically a result of refluxed contrast within the patient's vasculature, retrograde to the desired image area. The DyeVert™ System allows for the modulated reduction of contrast media during manual injections in

coronary or peripheral imaging procedures. The DyeVert™ System is a device for physician utilization during efforts to minimize total patient contrast volumes.

The DyeVert™ System consists of a sterile, single-use, fully-disposable apparatus. The source contrast container is connected to the reservoir chamber which has one tube directing contrast (through the manifold) to refill the injection syringe upon aspiration with preference to the diverted contrast volume prior to aspiration from the contrast source.

Intended Use:

The DyeVert™ Contrast Modulation System is intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.

Indications for Use:

The DyeVert™ Contrast Modulation System is to be used for the controlled infusion and contrast volume reduction of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 270 or 320 mgI/mL, Iohexol 300 or 350 mgI/mL and Iopamidol 370 mgI/mL.

Primary Predicate Device:

Trade Name/Proprietary Name:	DyeVert™ Contrast Modulation System
Manufacturer:	Osprey Medical, Inc.
Common Name:	Injector and Syringe, Angiographic
Classification:	II
CFR Reference:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K151746

Secondary Predicate Device:

Trade Name/Proprietary Name:	AVERT™ Contrast Modulation System
Manufacturer:	Osprey Medical, Inc.
Common Name:	Injector and Syringe, Angiographic
Classification:	II
CFR Reference:	21 CFR § 870.1650

Product Code: DXT
510(k) number(s) K151300

Comparison to the Predicate Device:

The DyeVert Contrast Modulation System is substantially equivalent to the previously cleared DyeVert and AVERT Contrast Modulation Systems, K151746 and K151300 respectively, in that they are both designed to control the infusion of radiopaque contrast media for angiographic procedures.

The proposed DyeVert™ System and predicate DyeVert™ System are identical systems with the exception of the labeling modification in accordance with clinical trial data and an additional model number for use with low viscosity contrast as indicated in the labeling.

- The proposed device consists of the same material and technical characteristics; and
- No changes have been made to the product performance specifications, sterilization process, manufacturing processes or risk assessment; and
- The intended use and fundamental scientific technology remains unchanged; and
- No new or different questions of safety or effectiveness are raised with the proposed modification.

The performance claim of contrast volume reduction is supported by AVERT System clinical trial data and raises no new or different questions of safety and effectiveness as compared to the predicate. Both the predicate and the DyeVert System have the identical intended use (i.e. “*controlled infusion of dye*”) and the performance claim does not affect its intended use. The application type, anatomical structure use, patient population and clinical setting remains unchanged. Inherent in the ‘control of contrast’ is ensuring that sufficient contrast is delivered to maintain adequate opacity during a procedure and simultaneously not creating a situation of excess risk (e.g. excess contrast or radiation exposure); as such, hazard analysis for contrast volume reduction performance and the study adverse event analysis demonstrates no new risk types or increased risk as compared to the predicate.

Summary of Non-Clinical Testing:

The DyeVert System design consists of standard luer lock connections, tubing, contrast diversion mechanism and a reservoir chamber. Performance specifications of the subject device remains unchanged from the previously cleared version. Bench testing was performed and/or leveraged to support this submission and results demonstrate the DyeVert System materials, design considerations and

manufacturing processes continue to meet product specifications and performance requirements. The following testing was successfully completed and/or leveraged within this submission:

- Device performance testing for high viscosity contrasts was leveraged and included flow rate, peak pressure, leak testing, contrast diversion, mechanical cycle testing and visual verifications to design specifications for specific contrasts and catheter configurations. Additional device performance testing for use with low viscosity contrasts was completed and included flow rate, peak pressure and contrast diversion. No additional testing was deemed necessary for low viscosity contrast use. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Sterilization conditions have been validated and leveraged in accordance with ISO 11135-1:2007, Sterilization of health care products – Ethylene Oxide Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices to provide a Sterility Assurance Level of 10⁻⁶. All testing passed.
- Packaging, shelf life and distribution testing was performed and leveraged. Distribution testing was conducted per ASTM D4169:2009 Standard Practice for Performance Testing of Shipping Containers and Systems. Testing included visual inspection, cycle testing, dye leak test, seal strength test and functional testing. All testing passed and demonstrated product performance met all prior established acceptance criteria. Packaging was deemed to be in compliance with ISO 11607 part 1 and 2:2006 Packaging for terminally sterilized medical devices. Seal strength testing was performed per ASTM F88-09 and seal integrity by dye penetration was performed per ASTM F1886-09. All testing passed.
- Biocompatibility testing was performed and leveraged in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part I: Evaluation and Testing. Testing included cytotoxicity, sensitization, irritation (intracutaneous reactivity), systemic toxicity and hemocompatibility. All testing passed and met prior established acceptance criteria.
- Simulated Use (Cath Lab) and Design Validation was performed and leveraged for injection pressure, contrast diversion and image analysis testing. Testing included an assessment of the ease of use, system set up and device priming ability (usability). Testing demonstrated no new or different question of safety or effectiveness.

No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for angiographic injectors and syringes.

Clinical Testing:

Human clinical data was leveraged and analyzed in support of this traditional 510(k) pre-market notification for controlled reduction of contrast volumes. A prospective, randomized, multi-center clinical evaluation was conducted using the Osprey Medical AVERT™ Contrast Modulation System. Leveraging of the clinical data is appropriate due to the high-level similarities of the devices and bench testing demonstrating the AVERT System represents worse case contrast percentage reduction across the full range of catheter/contrast configurations as compared to the DyeVert System. The study demonstrated a mean difference in contrast volume between the contrast modulation system and control group, achieving a relative and clinically significant contrast volume reduction, while maintaining adequate image quality and with no device related adverse events.

The clinical trial occurred with male and female subjects 18 years and older that were candidates for therapeutic percutaneous coronary intervention procedures with documented chronic kidney disease. The primary effectiveness endpoint was to demonstrate a mean reduction of contrast volume required in the treatment group as compared to the standard of care control group. The data demonstrated a non-normalized distribution of subjects with a mean reduction of 15.4% with a corresponding t-test p value of 0.0229. This corresponds to a 15.0% relative reduction of contrast volume used between the treatment and control groups. Specifically, diagnostic angiographic procedure demonstrated a 20.6% relative reduction and PCI angiographic procedures demonstrated a 17.2% relative reduction. There were no reported device related or unanticipated adverse events. For the sample size of 147 patients (treatment group), there was only one incident recorded as poor image quality related to the treatment device that resulted in the system being “shut off”. The result was low prevalence (<1%) and supports the effectiveness of minimizing contrast volume used while maintaining image quality.

Statement of Equivalence:

The DyeVert™ Contrast Modulation System has identical intended use, technological characteristics and fundamental scientific technology as the predicate devices. Based on this and data collected in accordance with Osprey Medical Quality System Procedures in compliance with ISO 13485:2003 *Medical Devices – Quality management systems - requirements for regulatory purposes* and EN ISO 14791:2012 *Risk management for medical devices*, the DyeVert System has been shown to be substantially equivalent under 21 CFR Part 807 subpart E.