



Food and Drug Administration  
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Silver Spring, MD 20993-0002

October 9, 2015

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

Re: K151746  
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: September 4, 2015  
Received: September 8, 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,



for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151746

Device Name

DyeVert(tm) Contrast Modulation System

Indications for Use (Describe)

The DyeVert™ Contrast Modulation System is to be used for the controlled infusion of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 320 mgI/mL, Iohexol 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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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## 510(k) Summary – K151746

This summary of 510(k) information is submitted in accordance with 21 CFR 807.92(c)

**510(k) Number:** K151746  
**Date Prepared:** June 26, 2015  
**Applicant Information:** Osprey Medical  
5600 Rowland Road Suite 250  
Minnetonka, MN 55343  
Phone: 952-955-8230  
Fax: 952-955-8171

**Contact Person:** Melanie Hess  
Vice President, Regulatory Affairs  
Phone: 952-955-8252  
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[Mhess@ospreymed.com](mailto:Mhess@ospreymed.com)

### Device Information:

Trade Name/Proprietary Name: DyeVert™ Contrast Modulation System  
Common/Classification Name: Angiographic Injector  
Classification: II  
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 (DyeVert System) allows for manual, physician-modulated contrast media injection during coronary or peripheral angiographic imaging. The Dyevert System consists of a sterile, single-use, fully-disposable apparatus which provides a secondary

fluid (contrast) pathway with a flow resistance feature to divert and store a portion of contrast in the reservoir chamber away from the patient. 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 of radiopaque contrast media for angiographic procedures with the following agents: Iodixanol 320 mgI/mL, Iohexol 350 mgI/mL and Iopamidol 370 mgI/mL.

**Predicate Device:**

Trade Name/Proprietary Name:	AVERT™ Contrast Modulation System
Common/Classification Name:	Angiographic Injector
Classification:	II
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K140425

**Predicate Indications for Use:**

The AVERT™ Contrast Modulation System is intended to be used for the controlled infusion 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.

**Comparison to the Predicate Device:**

The proposed DyeVert™ Contrast Modulation System is substantially equivalent in intended use, indication for use, method of operation, performance specifications and technical aspects to the predicate device, Osprey Medical AVERT™ Contrast Modulation System (K140425). The method of operation (mechanism of action) is entirely mechanical for both devices. Both devices divert and temporarily store

excess radiopaque contrast media away from the patient; and both function to reduce the users hand fatigue during routine angiographic procedures.

### **Summary of Non-Clinical Testing:**

Bench testing was performed and results demonstrate the DyeVert System materials, design considerations and manufacturing processes meet product specifications and performance requirements. The following testing was successfully completed:

- Device performance testing included flow rate, peak pressure, leak testing, contrast diversion, mechanical cycle testing and visual verifications to design specifications for specific contrasts and catheter configurations. 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<sup>-6</sup>. All testing passed.
- Packaging, shelf life and distribution testing was performed or 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.
- 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). All testing passed and met prior established acceptance criteria.

### **Clinical Testing:**

No clinical testing was performed to support this Traditional 510(k) Premarket Notification.

**Statement of Equivalence:**

The DyeVert System has a substantially equivalent intended use, indications for use statement, performance specifications and fundamental scientific technology as the predicate device. Based on this equivalence and the data collected in accordance with Osprey Medical Quality System Procedures in compliance with BS EN ISO 13485: 2012 *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.