DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

August 3, 2016

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

Re: K161505
Trade/Device Name: DyeVert NG Contrast Modulation System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: June 30, 2016
Received: July 5, 2016

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,

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
TBD K161505

Device Name
DyeVert NG Contrast Modulation System

Indications for Use *(Describe)*
The DyeVert™ NG 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: K161505

Date Prepared:	May 31, 2016
Submitter's Name/Address:	Osprey Medical 5600 Rowland Road Suite 250 Minnetonka, MN 55343
Contact Person:	Melanie Hess Vice President, Regulatory Affairs Tel: 952-955-8252 Fax: 952-955-8171 Mhess@ospreymed.com

Device Information:

Trade Name/Proprietary Name:	DyeVert™ NG Contrast Modulation System
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™ NG Contrast Modulation System (DyeVert System) is a compatible device to manual contrast injections and provides fluid pathway resistance modulation such that excess contrast volume (i.e. contrast that is not needed for diagnostic or therapeutic purposes) is minimized in the patient's vasculature and total contrast agent volume reduction occurs; while maintaining adequate image quality.

The DyeVert System consists of a disposable, single-use sterile device including a Reservoir and Diversion Valve. The device is positioned between a manual injection control syringe and an injection manifold via

the DyeVert stopcock. The diversion valve responds to the contrast injection pressure administered by the physician manually and modulates the amount of contrast diverted to the reservoir.

The DyeVert System has been designed for use with standard injection syringes and manifolds with Luer fittings that have been demonstrated to comply with ISO 594 "Conical fittings with a 6% luer taper for syringes, needles and certain other medical equipment". The DyeVert System is designed for use with contrast media and catheter configurations as listed in the Instructions for Use.

Intended Use:

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

Indications for Use:

The DyeVert™ NG 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.

Predicate Device:

Trade Name/Proprietary Name:	DyeVert™ Contrast Modulation System
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K153141

Reference Predicate Device(s):

Trade Name/Proprietary Name:	AVERT™ Contrast Modulation System
Manufacturer:	Osprey Medical Inc.
Product Code:	DXT
510(k) number(s)	K151300

Trade Name/Proprietary Name:	Medallion (VACLOK)™ Syringe
Manufacturer:	Merit Medical Systems, Inc.
Product Code:	FMF

510(k) number(s) K994253

Comparison to the Predicate Device:

The DyeVert™ NG System is substantially equivalent and unchanged from the predicate DyeVert™ System in that they are identical systems with the exception of the minor design modification to the reservoir and tubing inner diameter modification. Modification of the reservoir from a balloon style to a plunger style does not change the primary function of the reservoir as a passive component which temporarily holds diverted contrast until physician directed aspiration. There is no change to the diversion valve assembly mechanism for the diversion of excess contrast to the passive reservoir. No changes have been made to the product performance specifications, materials, sterilization process, directions for use, manufacturing processes or risk assessment. The intended use, indications for use and fundamental scientific technology remains unchanged. No new or different questions of safety or effectiveness were raised with the modification.

Summary of Non-Clinical Testing:

Bench testing was performed or leveraged from the predicate to support the DyeVert System and results demonstrate the DyeVert System meets all product specification and performance requirements. The following testing was successfully completed:

- Device performance testing was performed and leveraged for flow rate, peak pressure reduction, contrast diversion, mechanical cycle testing and visual verification to design specifications for specific contrasts and catheter configurations. Confirmation testing was conducted for priming, high pressure simulation, leak testing, reservoir capacity and tensile strength. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Sterilization conditions have been validated and leveraged from the predicate 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.
- Shelf-life, shipping 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 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.

- Biocompatible testing was leveraged from the predicate in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. Testing included cytotoxicity, sensitization, irritation (intracutaneous reactivity), systemic toxicity and hemocompatibility. All testing passed and meet prior established acceptance criteria.

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

Clinical Testing:

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

Statement of Equivalence:

The DyeVert System with the proposed modifications is substantially equivalent in intended use, indications for use and method of operation to the predicate DyeVert System. Based on the substantially equivalent assessment and data collected in accordance with Osprey Medical Quality System Procedure in compliance with EN ISO 13485:2012 *Medical Devices – Quality management systems – requirements for regulatory purposes* and EN ISO 14971:2012 *Risk management for medical devices*, the DyeVert System has been shown to be substantially equivalent under 21 CFR Part 807 subpart E.