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

Re: K171217
Trade/Device Name: DyeVert Plus Contrast Reduction System, DyeVert NG Contrast Reduction System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: April 25, 2017
Received: April 26, 2017

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,

Fernando Aguel-S

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)
K171217

Device Name
DyeVert™ NG Contrast Reduction System

Indications for Use (Describe)
The DyeVert™ NG Contrast Reduction 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.

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

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASTaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
510(k) Number (if known)
K171217

Device Name
DyeVert™ Plus Contrast Reduction System

Indications for Use (Describe)
The DyeVert™ Plus Contrast Reduction System consists of a Display and DyeVert Plus Disposable Kit. The system is to be used for contrast volume reduction and for the monitoring of radiopaque contrast media during angiographic or CT 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)

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- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."
510(k) Number: K171217
Submission Type: Special pre-market notification (510(k)), bundled
Date Prepared: April 25, 2017
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 Reduction 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)

Trade Name/Proprietary Name: DyeVert™ Plus Contrast Reduction 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™ NG and DyeVert™ Plus Contrast Reduction Systems are compatible to manual contrast injections and provide fluid pathway resistance modulation such that excess contrast volume (i.e. contrast that is not needed for diagnostic or therapeutic purposes also referred to as ‘refluxed contrast’) is minimized in the patient’s vasculature. This allows for a reduction in the total contrast agent volume during coronary or peripheral imaging to the patient; while maintaining adequate image quality.

Indications for Use:
The DyeVert™ NG Contrast Reduction 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.

The DyeVert™ Plus Contrast Reduction System consists of a Display and DyeVert Plus Disposable Kit. The system is to be used for contrast volume reduction and for the monitoring of radiopaque contrast media during angiographic or CT 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™ NG Contrast Reduction 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) K161505

Predicate Device:
Trade Name/Proprietary Name: DyeVert™ PLUS Contrast Reduction 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) K163054

Comparison to the Predicate Device:
The proposed devices are substantially equivalent to the previously cleared predicates, in that they are both designed for use during the controlled infusion of manual injection of radiopaque contrast media for angiographic procedures. The proposed devices have identical product performance specifications, sterilization processes, shelf life, packaging and benefit risk profiles. The subject 510(k) is to allow for the modification from machined to molded components. The fundamental scientific technology, principle of operation and primary mechanism of action remains unchanged. No new intended use, intended user or different questions of safety or effectiveness are raised with the proposed modification.

Summary of Non-Clinical Testing:
Bench testing was performed and/or leveraged to support this submission and results demonstrate the 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:

- Confirmatory device performance testing (design verification) included flow rate, peak pressure, contrast diversion, mechanical testing (high pressure use, leak and tensile strength) and visual verifications to design specifications for specific contrasts and catheter configurations. Durability testing (cycling) was leveraged. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Sterilization validation was leveraged – Sterilization conditions have been validated in accordance with ISO 11135-1:2014, 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.
- Simulated Use (Bench) design validation was leveraged and included the assessment of the ease of use, system set up and device priming ability (usability). In addition, design validation was leveraged for injection pressure, contrast diversion and image analysis testing. All testing passed.
- Packaging, shelf life and distribution testing was leveraged. Distribution testing was conducted per ASTM D4169:2016 Standard Practice for Performance Testing of Shipping Containers and Systems. Testing included visual inspection, cycle testing, dye leak/penetration 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.
- Confirmatory biocompatibility testing was performed in accordance with ISO 10993-1:2009 Biological Evaluation of Medical Devices – Part I: Evaluation and Testing. Testing included cytotoxicity, sensitization, irritation and acute systemic toxicity, and hemocompatibility. All testing passed and met 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 510(k) Premarket Notification.

**Statement of Equivalence:**
The proposed subject devices are substantially equivalent in intended use, indications for use statement and fundamental scientific technology as the predicate devices. Based on this and data analyzed 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 14791:2012 Risk management for medical devices, the proposed subject devices have been shown to be substantially equivalent under 21 CFR Part 807 subpart E.