October 25, 2018

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

Re: K181936
Trade/Device Name: DyeVert™ PLUS EZ Contrast Reduction System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 21, 2018
Received: September 25, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lydia S. Glaw -S
2018.10.25 13:40:54 -04'00'

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181936

Device Name
DyeVert™ PLUS EZ Contrast Reduction System

Indications for Use *(Describe)*

Display

The device consists of a display to be used with the DyeVert Plus Disposable Kit, DyeVert Plus EZ Disposable Kit or the DyeTect Contrast Monitoring Disposable Kit during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

DyeVert Plus EZ Disposable Kit

The DyeVert™ Plus EZ Contrast Reduction System consists of a Display and DyeVert Plus EZ 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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K181936 510(k) Summary

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

510(k) Number:	K181936
Submission Type:	Special pre-market notification (510(k))
Date Prepared:	17 July 2018

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

Device Information:

Trade Name/Proprietary Name:	DyeVert™ Plus EZ 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™ Plus EZ Contrast Reduction 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. Age, diabetes, moderate and severe chronic kidney disease and heart failure on presentation are leading factors for when to consider renal protection measures such as contrast minimization tools and processes.

The DyeVert Plus EZ Contrast Reduction System consists of the:

1. Contrast Monitoring Display (provided separately) and
2. DyeVert Plus EZ Disposable Kit.

The DyeVert Plus EZ Disposable Kit consists of the Smart Syringe and DyeVert Plus EZ Module. The DyeVert Plus EZ Disposable Kit is intended to be used with the Contrast Monitoring Display to allow monitoring and display of contrast volumes manually injected. Volumes are displayed and compared to physician entered contrast usage thresholds during angiographic procedures.

The DyeVert Plus EZ Module 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"; and the catheter configurations listed below. Utilization of catheters beyond those listed has not been substantiated.

Indications for Use:

Display

The device consists of a display to be used with the DyeVert Plus Disposable Kit, DyeVert Plus EZ Disposable Kit or the DyeTect Contrast Monitoring Disposable Kit during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

DyeVert Plus EZ Disposable Kit

The DyeVert™ Plus EZ Contrast Reduction System consists of a Display and DyeVert Plus EZ 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™ 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 device is substantially equivalent to the previously cleared predicate, in that they are both designed for use during the controlled infusion of manual injection of radiopaque contrast media for angiographic procedures. The proposed device has identical sterilization processes, shelf life and benefit-risk profiles. The subject device has nearly identical performance specifications that do not impact the principle of operation.

The subject device differs from the predicate device by providing ease of priming through a two-way check-valve and removing the shared fluid pathway between the diversion line and the contrast line.

The fundamental scientific technology and, principle of operation remain unchanged 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 previously performed and leveraged to support this submission. Results demonstrate the materials, design considerations and manufacturing processes meet product specifications and performance requirements. The following testing was successfully completed and leveraged within this submission:

Confirmatory device performance testing (design verification) included contrast diversion, accuracy, aspiration verification, functional testing after environmental conditioning and distribution simulation, pressure leak, shelf life, software verification and validation, sterilization adoption, biocompatibility and testing demonstrating compliance to IEC 60601-1, electrical safety for medical devices and IEC 60601-1-2 emissions and immunity for non-life supporting equipment through third party testing certification. T

The subject device use as intended was validated during simulated use validation. All testing passed and demonstrated product performance met all pre-established acceptance criteria.

- Contrast Diversion Testing was conducted to verify that the DyeVert Plus EZ System meets the performance specification. All testing results passed, meeting the acceptance criteria.
- Accuracy Testing was performed to demonstrate the DyeVert Plus EZ System measures contrast accounting with an accuracy of +/- 10%. All results passed.
- Air aspiration verification was performed based on ISO 10555-1 to confirm device integrity under vacuum. All tests passed.
- Simulated Use design validation was conducted during simulated use scenarios and following the Instructions for Use. Participants performed the entire cath lab procedure and provided feedback. Data and evaluation results were collected and analyzed. The results demonstrated that the acceptance criterion was met.
- Testing was performed after environmental conditioning and distributions simulation at T=0. Testing included visual inspection of packaging and labeling, functional testing of the Disposable Kit components and the Display. Package integrity and seal strength were testing. All testing results met the acceptance criteria.
- Pressure leak test was leveraged from that conducted with the predicate. The Module assembly components are nearly identical; and the bonding process used for the subject and predicate device is the same. The pressure joints are identical to those previously tested in K163054.
- Software development process was performed in accordance with IEC 62304:2006 Software life cycle process and testing conducted included verification of software requirement specifications rel. All testing passed.
- The subject device shelf life has been leveraged from that reported in the predicate 510(k).
- The DyeVert Plus EZ Disposable kit is EO sterilized using the same cycle as the predicate. The use of the cycle is supported by a sterilization adoption assessment conducted per AAMI TIR28. As such, the sterilization validation has been leveraged and is located in K163054.
- Confirmatory biocompatibility testing was performed in accordance with ISO 10993-1. 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 DyeVert Plus EZ Module and the updated Display software are substantially equivalent in intended use, indications for use statement and fundamental scientific technology as the predicate device. Based on this and data analyzed in accordance with Osprey Medical Quality System Procedure in compliance with 21 CFR 820, 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.