December 20, 2018

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

Re: K183267
Trade/Device Name: DyeVert™ NG Contrast Reduction System, DyeVert™ PLUS EZ Contrast Reduction System, DyeTect™ Contrast Monitoring Disposable Kit, Smart Syringe, 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: November 21, 2018
Received: November 27, 2018

Dear Melanie Hess:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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

Digitally signed by Lydia S. Glaw -S
Date: 2018.12.20 11:00:45 -05'00'

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)*
K183267

Device Name
DyeVert™ NG Contrast Reduction System, DyeVert™ PLUS EZ Contrast Reduction System, DyeTect™ Contrast Monitoring Disposable Kit, Smart Syringe, DyeVert™ PLUS EZ Contrast Reduction System

Indications for Use *(Describe)*

DyeVert™ NG Contrast Reduction System
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.

DyeVert™ Plus Contrast Reduction System
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.

DyeTect™ Contrast Monitoring Disposable Kit
The DyeTect™ Contrast Monitoring Disposable Kit consists of a Smart Syringe and Pressure Module to be used with the Contrast Monitoring Display during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

Smart Syringe
The Smart Syringe is to be used with the DyeVert™ Plus Contrast Reduction System or the Contrast Monitoring System. The DyeVert™ Plus Contrast Reduction 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. The Contrast Monitoring System is to be used 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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510(k) Summary

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

510(k) Number: K183267
Date Prepared: November 21, 2018

Submitter's Name/Address: Osprey Medical
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Subject Devices:

Trade Name/Proprietary Name:	DyeVert™ NG Contrast Reduction 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)
Predicate Device Trade Name:	DyeVert™ NG Contrast Reduction System
Predicate Device 510(k) Number(s):	K161505(initial), K171217 (subsequent design change from machined to injection-molded components)

Trade Name/Proprietary Name:	DyeVert™ Plus Contrast Reduction 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)
Predicate Device Trade Name:	DyeVert™ Plus Contrast Reduction System
Predicate Device 510(k) Number(s):	K163054 (initial), K171217 (subsequent design change from machined to injection-molded components)

Trade Name/Proprietary Name:	DyeTect™ Contrast Monitoring Disposable Kit
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
FDA Center/Branch:	CDRH/Interventional Cardiology Devices Branch (ICDB)
Predicate Device Trade Name:	DyeTect™ Contrast Monitoring Disposable Kit
Predicate Device 510(k) Number(s):	K163054

Trade Name/Proprietary Name:	Smart Syringe
Common Name:	Injector and Syringe, Angiographic
Classification Registration:	21 CFR § 870.1650
Product Code:	DXT
FDA Center/Branch:	CDRH/Interventional Cardiology Devices Branch (ICDB)
Predicate Device Trade Name:	Smart Syringe
Predicate Device 510(k) Number(s):	K171698

Trade Name/Proprietary Name:	DyeVert™ Plus EZ Contrast Reduction 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)
Predicate Device Trade Name:	DyeVert™ Plus EZ Contrast Reduction System
Predicate Device 510(k) Number(s):	K181936

Device Description:
The DyeVert NG, DyeVert PLUS and DyeVert PLUS EZ 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 total contrast agent volume during coronary or peripheral imaging; while maintaining adequate image quality. The DyeTect System is compatible to manual contrast injections and provides monitoring of the amount of contrast delivered to the patient. The Smart Syringe is also manufactured as a replacement component that can be used with the DyeVert Plus, DyeTect or DyeVert Plus EZ systems.

Indications for Use:
DyeVert™ NG Contrast Reduction System
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.

DyeVert™ Plus Contrast Reduction System
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.

DyeTect™ Contrast Monitoring Disposable Kit
The DyeTect™ Contrast Monitoring Disposable Kit consists of a Smart Syringe and Pressure Module to be used with the Contrast Monitoring Display during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

Smart Syringe
The Smart Syringe is to be used with the DyeVert™ Plus Contrast Reduction System or the Contrast Monitoring System. The DyeVert™ Plus Contrast Reduction 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. The Contrast Monitoring System is to be used 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.

Comparison to the Predicate Device:
The only change between the predicate devices and the proposed new devices is the sterilization process. Both the existing sterilization process, and the proposed new sterilization process, utilize ethylene oxide gas to sterilize disposable devices. Both processes use a half-cycle overkill approach, and both cycles meet established acceptance criteria for EO residuals on finished devices per ISO 10993-7:2008. Both processes have been fully qualified using ISO 11135:2014.

Summary of Non-Clinical Testing:
Full qualification testing was performed 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:

- Sterilization validation was performed – Sterilization conditions have been validated in accordance with ISO 11135:2014, 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.
- Residuals testing was performed in accordance with ISO 10993-7:2008 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals. All testing passed and met 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 sterilized using the new sterilizer and revised sterilization process are substantially equivalent in intended use, indications for use statement and fundamental scientific technology as the predicate devices sterilized using current processes. Based on this and data analyzed in accordance with Osprey Medical Quality System Procedure in compliance with EN ISO 13485:2016 *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