October 17, 2019

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

Re: K190102
Trade/Device Name: DyeVert Plus Contrast Reduction System, DyeVert Plus EZ Contrast Reduction System, DyeTect Contrast Monitoring System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: September 13, 2019
Received: September 16, 2019

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For Alan Stevens
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
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)*
K190102

Device Name
DyeVert™ Plus Contrast Reduction System, DyeTect™ Contrast Monitoring System, DyeVert™ Plus EZ Contrast Reduction System

Indications for Use *(Describe)*
DyeVert™ Plus Contrast Reduction System

Smart Monitor
The device consists of a Smart Monitor 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 Disposable Kit
The DyeVert™ Plus Contrast Reduction System consists of a Monitor 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.

DyeVert™ Plus EZ Contrast Reduction System

Smart Monitor
The device consists of a Smart Monitor 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 Monitor 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.

DyeTect™ Contrast Monitoring System

Smart Monitor
The device consists of a Smart Monitor 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.

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

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 As required by 21CFR 807.92(c)
510(k) Number: K190102
Submission Type: Traditional pre-market notification (510(k))
Date Prepared: 16 October 2019

Submitter's Name/Address: Osprey Medical Inc.
5600 Rowland Road Suite 250
Minnetonka, MN 55343

Contact Person: Melanie Hess
Vice President Regulatory Affairs, Compliance and Quality
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Device Information:
Trade Name/Proprietary Name(s): DyeVert™ Plus Contrast Reduction System
DyeTect™ Contrast Monitoring System
DyeVert™ Plus EZ Contrast Reduction System
Manufacturer: Osprey Medical Inc.
Common Name: Injector and Syringe, Angiographic
Regulation Name: Angiographic injector and syringe
Classification Registration: 21 CFR § 870.1650
Product Code: DXT

Device Description:
The Osprey Medical DyeVert™ Plus 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. The DyeVert™ Plus Contrast Reduction System consists of a non-sterile monitor and EO sterilized disposable kit.
The DyeTect™ Contrast Monitoring Disposable Kit consists of EO sterilized Smart Syringe and Pressure Module. The system allows for real-time, wireless, monitoring and display of manually injected contrast volumes. Volumes are displayed and compared to a physician entered contrast usage threshold during angiographic procedures. The system provides a visual and audible indication of when the cumulated volume injected into the patient is approaching a physician determined contrast volume threshold.

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. The DyeVert™ Plus EZ Contrast Reduction System consists of a non-sterile monitor and EO sterilized disposable kit.

Indications for Use:
DyeVert™ Plus Contrast Reduction System
Smart Monitor
The device consists of a Smart Monitor 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 Disposable Kit

The DyeVert Plus Contrast Reduction System consists of a Monitor 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.

DyeVert™ Plus EZ Contrast Reduction System
Smart Monitor
The device consists of a Smart Monitor 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 Contrast Reduction System consists of a Monitor 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 System
Smart Monitor
The device consists of a Smart Monitor 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.

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

Predicate Device:

Trade Name/Proprietary Name:	DyeVert™ Plus Contrast Reduction System DyeTect™ Contrast Monitoring System
Manufacturer:	Osprey Medical, Inc.
Common Name:	Injector and Syringe, Angiographic
Classification:	II
Regulation Name:	Angiographic injector and syringe
Regulation:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K163054

Trade Name/Proprietary Name:	DyeVert™ Plus EZ Contrast Reduction System
Manufacturer:	Osprey Medical, Inc.
Common Name:	Injector and Syringe, Angiographic
Classification:	II
Regulation Name:	Angiographic injector and syringe
Regulation:	21 CFR § 870.1650
Product Code:	DXT
510(k) number(s)	K181936

Comparison to the Predicate Device:

Comparison of Indications for use
The proposed system's Indications for Use are the same.

Comparison of Technological Characteristics
The disposable kits components of the subject systems have not changed. The Smart Monitor component of the subject systems is the only modification proposed in this submission and a comparison to the predicate is provided below. The monitor is non-patient contacting.

The Smart Monitor, like the predicate (Display) is a multiuse, non-sterile, and non-disposable device that allows for real-time monitoring and display of manually injected contrast volumes when used with the compatible disposable kits. The Smart Monitor has the same intended use as the predicate. Identical to the predicate, the Smart Monitor communicates wirelessly via a Bluetooth connection with the disposables. The Smart Monitor differs from the predicate display in design, materials and software. The Smart Monitor provides additional memory, can receive and execute software updates automatically or manually via WiFi, includes optional voice alerts, and can export de-identifiable or identifiable case information via WiFi for further analysis.

Device Characteristic	Smart Monitor (Proposed)	CMW Display (Predicate K181936)
Principle of Operation	Real-time wireless monitoring and display of contrast volumes manually injected.	Real-time wireless monitoring and display of contrast volumes manually injected.
Product Code/Regulation	DXT / 21 CFR § 870.1650	DXT / 21 CFR § 870.1650
User Interface	Touchscreen, user-preset volume variables, proactive monitoring through user indicators, electronic display, audio alarms	Touchscreen, user-preset volume variables, proactive monitoring through user indicators, electronic display, audio alarms
Power Source	AC Power via cable. Built-in 19.1 watt hour rechargeable lithium polymer battery as backup power supply.	AC Power via cable
Screen	7.9 inch backlit capacitive display	10.4 inch LCD backlit capacitive display
Housing	iPad Mini 4	Polycarbonate/ABS housing
Display Memory	128 GB	32GB
Packaging Materials	Corrugated shipping box, polyurethane ester	C-fluted 275lb Kraft colored box with foam
App Framework	QT 5.8.0	QT 5.8.0

Device Characteristic	Smart Monitor (Proposed)	CMW Display (Predicate K181936)
Bluetooth Stack	CoreBluetooth (iOS)	BlueZ (Linux)
Software Updates	Wi-Fi via. Mobile Device Management (MDM)	USB
Video Player	iOS (AVPlayer)	Qt (QtMultimedia 5.8)
Settings Storage	iOS (NSUserDefaults)	Text File
Case Database Format	SQLite File	SQLite File
Shelf Life	No established life expectancy labeled to return to Osprey Medical for repair/servicing	No established life expectancy labeled to return to Osprey Medical for repair/servicing
Wireless Connections	Wifi, and Bluetooth	Bluetooth
User Settings	Warning Tones, Threshold Warning %, Tone Selection, Pause Voice Alert, Start in Pause Mode, Pause Lock, Case ID & Renal Function Checkbox, Case History	Warning Tone, Warning Tone Volume, Threshold Warning %, Tone Selection, Screen Brightness, Pause Lock, Language, Start in Pause Mode, Case History, Date/Time
Case Export	AWS S3	USB

The differences in technology were assessed during Design Verification bench testing, Software Validation, Electrical Safety, EMC, Cybersecurity and Human Factors testing and the results of the testing demonstrate that the changes do not raise questions of safety and effectiveness.

Summary of Non-Clinical Testing:
Bench 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 provided within this submission:

- Software development process was conducted in accordance with IEC 62304:2006 Software life cycle process and testing was performed, which included verification of all software requirement specifications.

- The Smart Monitor has been tested for Electrical Safety and EMC compatibility per IEC 60601-1, 60601-1-2 and ANSI C63.27.
- The wireless communication of the Smart monitor complies with part 15 of the FCC Rule.
- Design verification testing was conducted with the DyeVert Plus, DyeVert Plus EZ, and the DyeTect Disposable kits and which included cumulative volume accuracy, pause/resume of the system with Module pause, pause/resume of the system based on stopcock position (DyeVert Plus only), system resume with pressure transducer and no count of injection if contrast is sent back to the contrast source.
- Distribution testing was conducted after environmental conditioning per ASTM D4169-16 and ISTA P2A.
- Human Factors testing was performed in accordance with FDA guidance Applying Human Factors and Usability Engineering to Medical Devices, issued February 2016, BS EN 62366-1 Medical Devices – application of usability engineering to medical devices, 2015; and AAMI/ANSI HE75 2009/(R)2013 Human factors engineering – Design of medical devices.
- Cybersecurity evaluation was performed in accordance with FDA guidance, Content of premarket submissions for management of cybersecurity in medical devices, issued October 2014.

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 Contrast Reduction System, DyeVert Plus EZ Contrast Reduction System and DyeTect Contrast Monitoring Systems are substantially equivalent to the predicate devices as they have the same intended use and indications for use. Based on this and data analyzed in accordance with Osprey Medical Quality System Procedure in compliance with 21 CFR 820, 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.