March 8, 2017

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

Re: K163054

Trade/Device Name: DyeVert™ Plus Contrast Modulation/Monitoring System, Contrast Monitoring System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector And Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: February 3, 2017
Received: February 6, 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
510(k) Number (if known)
K163054

Device Name
DyeVert™ Plus Contrast Modulation/Monitoring System, Contrast Monitoring System

Indications for Use (Describe)
Display
The device consists of a display to be used with the DyeVert Plus Disposable Kit or the Contrast monitoring Disposable Kit during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.

DyeVert Plus Disposable Kit
The DyeVert™ Plus Contrast Modulation/Monitoring 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.

Contrast Monitoring Disposable Kit
The device 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.

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

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510(k) Summary

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

510(k) Number: K163054
Date Prepared: October 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™ Plus Contrast Modulation/Monitoring 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: Contrast Monitoring 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 Contrast Modulation/Monitoring System is a compatible system to manual contrast injections and provides fluid pathway resistance modulation and/or monitoring 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 DyeVert Plus Contrast Modulation/Monitoring System consists of the Display and the DyeVert Plus Disposable Kit.

The Contrast Monitoring System is a component of the DyeVert™ Plus Contrast Modulation/Monitoring System and also provided separately. 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. This allows for attentive physician decision-making of total contrast volume use during a patient case while allowing the physician’s primary focus to remain on the image and therapeutic need of imaging. When sold separately, the Contrast Monitoring System consists of the Display and the Contrast Monitoring Disposable Kit.

Indications for Use:
Display
The device consists of a display to be used with the DyeVert Plus Disposable Kit or the Contrast monitoring Disposable Kit during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.
DyeVert Plus Disposable Kit
The DyeVert™ Plus Contrast Modulation/Monitoring 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.

Contrast Monitoring Disposable Kit
The device 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.

Primary Predicate Device:
Trade Name/Proprietary Name: DyeVert™ Contrast Modulation 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

Secondary Predicate Device:
Trade Name/Proprietary Name: CMS™ Contrast Monitoring 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) K142081

Comparison to the Predicate Device:
The proposed devices are substantially equivalent to the previously cleared DyeVert Contrast Modulation Systems (K161505) and CMS Contrast Monitoring System (K142081) respectively, 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 and benefit risk profiles. 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 modifications.

Summary of technical characteristics comparison

<table>
<thead>
<tr>
<th>Technical Characteristic</th>
<th>Proposed Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intended Use</td>
<td>Intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.</td>
<td>Intended to be used for the controlled infusion of radiopaque contrast media for angiographic procedures.</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>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.</td>
<td>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.</td>
</tr>
<tr>
<td>Indications for Use (Display/Syringe)</td>
<td>To be used during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.</td>
<td>To be used during angiographic or CT procedures requiring controlled infusion of radiopaque contrast media.</td>
</tr>
<tr>
<td>Touchscreen</td>
<td>Capacitive touchscreen, Resolution 1280x800</td>
<td>Resistive touchscreen, Resolution 800x600</td>
</tr>
</tbody>
</table>
## Technical Characteristic

<table>
<thead>
<tr>
<th>Proposed Device</th>
<th>Predicate Device</th>
</tr>
</thead>
<tbody>
<tr>
<td>User access</td>
<td></td>
</tr>
<tr>
<td>Multiple USB, 1 internal user accessible (Osprey User only)</td>
<td>1 external USB</td>
</tr>
<tr>
<td>Memory</td>
<td></td>
</tr>
<tr>
<td>MicroSD socket with 32GB class 10 card</td>
<td>External flash memory using a SPI interface</td>
</tr>
<tr>
<td>Alarms</td>
<td></td>
</tr>
<tr>
<td>Variable audio</td>
<td>Limited audio</td>
</tr>
<tr>
<td>DyeVert Module</td>
<td></td>
</tr>
<tr>
<td>Diversion valve with reservoir; includes sensors, electronics, circuit board and pressure transducer to allow wireless positioning identification. Compatible with Contrast Monitoring Display</td>
<td>Diversion valve with reservoir (does not include additional wireless positioning components) Not compatible with Contrast Monitoring Display.</td>
</tr>
<tr>
<td>Syringe</td>
<td></td>
</tr>
<tr>
<td>Contrast injection syringe; includes Hall Effect sensors, electronics and circuit board to allow wireless positioning identification and communication.</td>
<td>Contrast injection syringe with IR light sensing positioning identification (does not include additional wireless communication components)</td>
</tr>
<tr>
<td>Communication</td>
<td></td>
</tr>
<tr>
<td>Bluetooth communications to Display</td>
<td>Hard wire communications to Display</td>
</tr>
<tr>
<td>Power</td>
<td></td>
</tr>
<tr>
<td>Internal Battery</td>
<td>Hard Wire</td>
</tr>
<tr>
<td>Visual Indicators</td>
<td></td>
</tr>
<tr>
<td>Blinking and/or solid LED (green/amber) indicates status; additional blinking allowing additional status communication during disposable pairing through Bluetooth.</td>
<td>Solid LED (green/amber) indicates status</td>
</tr>
<tr>
<td>Compatible Catheter Configurations</td>
<td></td>
</tr>
<tr>
<td>Diagnostic 4Fr, 5Fr, 6Fr</td>
<td>Diagnostic 4Fr, 5Fr, 6Fr</td>
</tr>
<tr>
<td>Guide 5Fr, 6Fr, 7Fr</td>
<td>Guide 5Fr, 6Fr, 7Fr</td>
</tr>
<tr>
<td>Guide with RX 6Fr, 7Fr</td>
<td>Guide with RX 6Fr, 7Fr</td>
</tr>
<tr>
<td>Guide with OTW 6Fr, 7Fr</td>
<td>Guide with OTW 6Fr, 7Fr</td>
</tr>
<tr>
<td>Sterilization</td>
<td></td>
</tr>
<tr>
<td>EO sterilization to $10^{-6}$</td>
<td>EO sterilization to $10^{-6}$</td>
</tr>
</tbody>
</table>

## 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:

- Device performance testing included visual verifications to design specifications, accuracy testing of cumulative and individual injection volume measurement along with display verification, compatibility with disposable kits and testing demonstrating compliance to IEC 60601-1 3.1 edition, electrical safety for medical devices and IEC 60601-1-2 (2007) emissions and immunity for non-life supporting equipment through third party testing certification. In addition, device performance testing for compatibility with contrast media and catheter configurations was leveraged and included flow rate, peak pressure, leak testing, contrast diversion, mechanical cycle testing and visual verifications to design specifications for specific contrasts and catheter configurations. All testing passed and demonstrated product performance met all prior established acceptance criteria.
- Sterilization – 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.
- Software development process was in accordance with IEC 62304:2006 Software life cycle process and testing was performed and included verification of all software requirement specifications. All testing passed.
- Simulated Use (Bench) design validation was performed and included the assessment of priming, disposable wireless pairing and assessment of the ease of use, system set up and device priming ability (usability). In addition, design validation was performed and leveraged for injection pressure, contrast diversion and image analysis testing. Testing demonstrated no new or different question of safety or effectiveness.
Packaging, shelf life and distribution testing was performed and 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.

Biocompatibility testing was performed and leveraged 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.