DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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July 7, 2017

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

Re: K171698
Trade/Device Name: Smart Syringe
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: DXT
Dated: June 7, 2017
Received: June 8, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171698

Device Name
Smart Syringe

Indications for Use *(Describe)*
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.

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: K171698

Submission Type: Special pre-market notification (510(k))

Date Prepared: June 07, 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
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Mhess@ospreymed.com

Device Information:

Trade Name/Proprietary Name:	Smart Syringe
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 Smart Syringe is a component to the DyeVert™ Plus Contrast Reduction System and Contrast Monitoring System. The Smart Syringe is not intended to be used independently. The Smart Syringe is a control syringe with wireless communication capability to the Osprey Medical DyeVert Plus and Contrast Monitoring Display.

Indications for Use:

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.

Predicate Device:

Trade Name/Proprietary Name:	DyeVert™ Plus Contrast Reduction System and 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)	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 product performance specifications, sterilization processes, shelf life, direct packaging 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 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 flow rate, peak pressure, contrast diversion, monitoring accuracy, fluid ingress, system compatibility, durability testing (cycling), visual verifications to design specifications 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. 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.
- Software development process was in accordance with IEC 62304:2006 Software life cycle process and testing was performed and leveraged which included verification of all software requirement specifications. All testing passed.
- Simulated Use (Bench) design validation was leveraged 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 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 device is 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 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 device has been shown to be substantially equivalent under 21 CFR Part 807 subpart E