DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 30, 2017

AngioDynamics, Inc.
Robin Fuller
Sr. Manager, Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K163356
Trade/Device Name: Pulse* Spray and Uni*Fuse Infusion Systems
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: April 4, 2017
Received: May 5, 2017

Dear Robin Fuller:

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,

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)*
K163356

Device Name
Pulse* Spray Infusion System,
Uni*Fuse Infusion System

Indications for Use *(Describe)*
The Pulse*Spray System, PRO Infusion Catheter, and its related components, are intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature.

The Uni*Fuse Infusion System is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature.

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 FOR THE

ANGIODYNAMICS, INC. PULSE*SPRAY AND UNI*FUSE INFUSION SYSTEMS

Date Prepared: 10 January 2017

A. Sponsor:

AngioDynamics, Inc.

26 Forest Street

Marlborough, MA 01752

B. **Contact:**

Robin Fuller
Sr. Manager Regulatory Affairs

Tel: 508-658-7986

Fax: 508-658-7976

Email: RFuller@angiodynamics.com

Subject Device:

Trade Name:	AngioDynamics Pulse*Spray and Uni*Fuse Infusion Systems
Common Name:	Infusion Catheter
Regulation Number;	21 CFR 870.1210
Regulation Name:	Continuous Flush Catheter
Regulatory Class:	Class II
Product Code:	KRA
Classification Panel:	Cardiovascular

Predicate Device:

Trade Name:	AngioDynamics Pulse*Spray and Uni*Fuse Infusion Systems
510(k) Reference:	K961763
Common Name:	Infusion Catheter
Regulation Number;	21 CFR 870.1210
Regulation Name:	Continuous Flush Catheter
Regulatory Class:	Class II
Product Code:	KRA
Classification Panel:	Cardiovascular

C. Device Description:

The Pulse*Spray Catheter is packaged in a kit configuration. The following components are sold in the Pulse*Spray Infusion Catheter Kits:

•PRO (Pressure Responsive Outlet) Infusion Catheter with longitudinal slits at the distal end. Slits are located at 90^{o} intervals around the catheter. Radiopaque markers on the catheter shaft indicate the active infusion pattern.
•Occluding Guidewire or Occluding Ball Wire which occludes the distal end of the PRO Infusion Catheter. The Occluding Guidewires or Occluding Ball Wires have proximal markers for occlusion position verification.
•1 mL Syringe and finger flange
•10 mL Syringe
•20 mL Syringe
•Y-Connector with Tuohy-Borst adapter
•Dual Check Valve

The Uni*Fuse Catheters are sold in only one configuration, with an occluding guidewire.

D. Intended Use/Indications for Use:

The Pulse*Spray System, PRO Infusion Catheter, and its related components, are intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature.

The Uni*Fuse Infusion System is intended for the administration of fluids, including thrombolytic agents and contrast media, into the peripheral vasculature

E. Summary of Similarities and Differences in Technology Characteristics and Performance:

The proposed device has the same design and technical characteristics as the predicate device. The purpose of this 510(k) submission is to introduce into commercial distribution a modified AngioDynamics, Inc. Pulse*Spray and Uni*Fuse Infusion catheter. The modification is a change in the catheters shaft material and hub material.

Beyond the two material changes, the proposed and predicate devices are identical in regards to design, materials, packaging and sterilization to the predicate device. There are no changes being made to any of the accessories provided within the Pulse*Spray and Uni*Fuse Infusion catheters.

F. Performance Data:

The performance testing included non-clinical bench testing. The following tests were performed.

- CatheterTensile
- Static Burst
- Catheter Flow Rate
- Catheter Occlusion Tip Durability
- Catheter Temperature Condition
- Catheter Dispersion and Occlusion Seal
- Biocompatibility per ISO 10993-1

G. Conclusion:

The results of the non-clinical testing and a comparison of similarities and differences demonstrate that the proposed and predicate devices are substantially equivalent.