DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 21, 2017

AngioDynamics, Inc.
Teri Juckett
Regulatory Affairs Manager
603 Queensbury Avenue
Queensbury, NY 12804

Re: K170258
Trade/Device Name: SpeedLyser Infusion Catheter Kit
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA
Dated: January 27, 2017
Received: January 27, 2017

Dear Teri Juckett:

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,

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)*
K170258

Device Name
SpeedLyser Infusion Catheter Kit

Indications for Use *(Describe)*
The SpeedLyser Infusion Catheter Kit 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.

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510(K) SUMMARY FOR THE
ANGIODYNAMICS, INC. SPEEDLYSER INFUSION CATHETER KIT

Date Prepared: 27 January 2017

A. Sponsor:

AngioDynamics, Inc.
10 Glens Falls Technical Park
Glens falls, New York, 12801

B. **Contact:**

Teri Juckett
Manager Regulatory Affairs
Tel: 518-795-1142
Fax: 518-742-4323
Email: tjuckett@angiodynamics.com

Subject Device:

Trade Name:	AngioDynamics SpeedLyser Infusion Catheter Kit
Common Name:	Infusion Catheters
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 SpeedLyser Infusion Catheter Kit
510(k) Reference:	K033443
Common Name:	Infusion Catheters
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 SpeedLyser Infusion Catheter Kit includes a variety of related components including:

- 0.018" Guidewire
- 21 Gauge Entry Needle
- Non-Vented Caps (2)

The SpeedLyser catheter consists of the outer 5F catheter and an occluding 3F catheter. The outer 5F catheter is designed with slits along the shaft to provide optimal distribution of lytic over a thrombosed graft length.

D. Intended Use/Indications for Use:

The SpeedLyser Infusion Catheter Kit 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 similar materials, design, and technical characteristics as the predicate device. The purpose of this 510(k) submission is to introduce into commercial distribution a modified AngioDynamics SpeedLyser catheter. There are two modifications. The first modification is to the material used to mold the hub of the 5F catheter. The second modification is being made material used to extrude the 3F and 5F catheter shafts.

F. Performance Data:

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

- Hub to Shaft Tensile (3F Occluding Catheter and 5F Infusion Catheter)
- Shaft Tensile (3F Occluding Catheter and 5F Infusion Catheter)
- Print Adhesion
- Gel Shots
- Biocompatibility per ISO 10993-1

G. Conclusion:

Based upon successful results of testing and responses to questions posed within FDA's 510(k) Decision-Making Tree, the proposed device is determined to be substantially equivalent.

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