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

April 28, 2017

Angiodynamics, Inc.
Teri Juckett
Regulatory Affairs Manager
603 Queensbury Ave
Queensbury, New York 12804

Re: K161596
Trade/Device Name: AngioDynamics, Inc. Soft-Vu, Mariner, Accu-Vu and AngiOptic Angiographic Catheters
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: March 28, 2017
Received: March 29, 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 yours,

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)*
K161596

Device Name
AngioDynamics, Inc. Soft-Vu, Mariner, Accu-Vu and AngiOptic Angiographic Catheters

Indications for Use *(Describe)*
AngioDynamics Angiographic Catheters are for use where angiographic diagnosis is indicated.

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 -- K161596
ANGIODYNAMICS, INC. ANGIOGRAPHIC CATHETERS
(SOFT-VU, MARINER, ACCU-VU, AND ANGIOPTIC)

Date Prepared: 08 June 2016

A. Sponsor:

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804

B. Contact:

Teri L. Juckett
Manager, Global Regulatory Affairs
Tel: 518-795-1142
Email: tjuckett@angiodynamics.com

C. Device Name:

Trade Name:	AngioDynamics Angiographic Catheters (Soft-Vu, Mariner, Accu-Vu and AngiOptic)
Common/Usual Name:	Angiographic Catheters
Classification Name:	Catheter, Intravascular, Diagnostic (21CFR§870.1200, Class II, Pro-Code DQO)
Classification Panel:	Cardiovascular

D. Predicate Device:

Trade Name:	AngioDynamics Angiographic Catheters (Soft-Vu, Mariner, Accu-Vu and AngiOptic)
Common/Usual Name:	Angiographic Catheters
Classification Name:	Catheter, Intravascular, Diagnostic (21CFR§870.1200, Class II, Pro-Code DQO)
Classification Panel:	Cardiovascular
Premarket Notification:	K151724, K112452

E. Device Description:

AngioDynamics Angiographic Catheters are sterile, single use, disposable devices designed to delivery radiopaque contrast media to selected sites in the vascular system.

F. Indications for Use:

AngioDynamics Angiographic Catheters are for use where angiographic diagnosis is indicated.

G. Intended Use:

The intended use of the AngioDynamics Angiographic Catheters is to deliver radiopaque contrast media to the vasculature during angiographic procedures.

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

I. 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 modified AngioDynamics Angiographic Catheters which includes material changes to the shaft, tip, and hub of the device.

J. Performance Data:

The proposed AngioDynamics Angiographic Catheters and the predicate AngioDynamics Angiographic Catheters are substantially equivalent to the specified predicate devices based on a comparison of technological characteristics and the results of non-clinical performance and material testing, which include:

- Static Pressure
- Hub/Injector Connection
- Tip Stability
- Tensile
- Radiopacity
- Coating Activation
- Friction
- Particulate
- Biocompatibility per ISO 10993-1

K. 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.