July 18, 2018

AngioDynamics, Inc.
Ms. Teri Juckett
Sr. Regulatory Affairs Manager
603 Queensbury Avenue
Queensbury, New York 12804

Re: K173762
Trade/Device Name: AngioDynamics, Inc. Angiographic Catheters (Soft-Vu and Mariner)
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II
Product Code: DQO
Dated: June 28, 2018
Received: July 2, 2018

Dear Ms. 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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Gregory O'Connell
2018.07.18 08:43:24 -04'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K173762

Device Name
AngioDynamics, Inc. Angiographic Catheters (Soft-Vu and Mariner)

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.

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510(K) SUMMARY FOR THE
ANGIODYNAMICS, INC. ANGIOGRAPHIC CATHETERS
(SOFT-VU AND MARINER)
K173762

Date Prepared: 17 July 2018

A. Sponsor:

AngioDynamics, Inc.
603 Queensbury Avenue
Queensbury, NY 12804

Phone Number: 518-795-1142

B. Contact:

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

C. Device Name:

Trade Name:	AngioDynamics Angiographic Catheters (Soft-Vu and Mariner)
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 and Mariner)
Common/Usual Name:	Angiographic Catheters
Classification Name:	Catheter, Intravascular, Diagnostic (21CFR§870.1200, Class II, Pro-Code DQO)
Classification Panel:	Cardiovascular
Premarket Notification:	K161596

E. Device Description:

AngioDynamics Angiographic Catheters are sterile, single use, disposable devices designed to deliver radiopaque contrast media to selected sites in the vascular system. AngioDynamics Soft-Vu and Mariner Catheters come in the following sizes/structures:

	Soft-Vu	Mariner
French Size	4F, 5F, 6F	4F, 5F
Shaft	Braided and Non-Braided	Braided and Non-Braided
Tip	Non-Braided	Non-Braided
Coating	Non-Coated	Coated
Lengths	25cm – 150cm	25cm – 150cm

The only change presented in this 510(k) submission is a change to the colorant and the addition of heat and light stabilizers to the braided catheter shaft.

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:

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 Soft-Vu and Mariner braided catheters with a change to the colorant and the addition of heat and light stabilizers to the shaft. This change also introduces four new tip shapes including the following: ARC, NaviGate 1,2,3,4,5, Omega, and Sharp Angle.

I. 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
- Coating Activation
- Friction
- Particulate
- Biocompatibility per ISO 10993-1

J. 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.