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

January 6, 2017

AngioDynamics, Inc.
Teri Juckett
Regulatory Affairs Manager
10 Glens Falls Technology Park
Glens Falls, New York 12801

Re: K163141
Trade/Device Name: NAMIC ClearaCIL Contrast Injection Lines
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: November 8, 2016
Received: November 9, 2016

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,

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)*
K163141

Device Name
NAMIC ClearaCIL Contrast Injection Lines

Indications for Use *(Describe)*

NAMIC ClearaCIL Contrast Injection Lines are intended to be used in fluid management procedures.

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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K163141

510(k) Summary

Date Prepared: 06 January 2017

A. Submitter Information:

AngioDynamics Inc.
10 Glens Falls Technology Park
Glens Falls, New York 12801
Tel: (518) 795-1142
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Contact: Teri Juckett,
Manager, Regulatory Affairs
Email: tjuckett@angiodynamics.com

B. Proposed Device:

Trade Name:	NAMIC ClearaCIL Contrast Injection Lines
Common Name:	High Pressure Lines
Classification Name:	Diagnostic Intravascular Catheter
Product Code:	DQO, 870.1200
Class:	II

C. Predicate Device:

Trade Name:	NAMIC ClearaCIL Contrast Injection Lines
Common Name:	High Pressure Lines
Classification Name:	Diagnostic Intravascular Catheter
Product Code:	DQO, 870.1200
Class:	II

D. Device Description

The NAMIC ClearaCIL Contrast Injection Lines are used to establish a conduit for the passage of fluids from a vascular power injector to a catheter. The Luer fittings are used to establish a secure, leak-free connection to the injector and catheter.

E. Indications for Use

NAMIC ClearaCIL Contrast Injection Lines are intended to be used in fluid management procedures.

F. Summary of Similarities and Differences in Technological Characteristics and Performance

The proposed devices have similar materials, design, and technical characteristics as the predicate devices. The purpose of this 510(k) submission is to introduce into commercial distribution a modified NAMIC ClearaCIL Contrast Injection Lines which includes a material change.

G. Performance Data

The proposed NAMIC ClearaCIL Contrast Injection Lines and the predicate NAMIC ClearaCIL Contrast Injection Lines are substantially equivalent to the specific predicate devices based on a comparison of technological characteristics and the results of non-clinical performance and material testing, which include:

- Luer Bond Flex Strength
- Luer Bond Tensile Strength
- Air Leak Resistance
- Tubing Transparency
- Hydrodynamic Fluid Leak Resistance
- Biocompatibility per ISO 10993-1

H. Conclusion

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