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

February 5, 2015

AngioDynamics Inc.
Mr. Michael P. Hanley
Specialist, Global Regulatory Affairs
26 Forest Street
Marlborough, MA 01752

Re: K142889
Trade/Device Name: Celerity™ PICCTip Confirmation System
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: December 12, 2014
Received: December 15, 2014

Dear Mr. Hanley:

This letter corrects our substantially equivalent letter of January 27, 2015.

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" (21CFR 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,

for Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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)*
K142889

Device Name
Celerity PICC Tip Configuration System

Indications for Use *(Describe)*

The Celerity System is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Celerity System is indicated for use as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-Wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave; including
-Atrial fibrillation
-Atrial flutter
-Severe tachycardia
-Pacemaker-driven rhythm
- Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

angiodynamics

December 12, 2014
Re: K142889-Supplement

510(k) Summary : K142889

Date Prepared: October 01, 2014

A. Submitter Information

Submitter: Angiodynamics Inc.
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Email: lvarroso@angiodynamics.com

B. Trade Name

Trade Name:	Celerity™ PICC Tip Confirmation System
Common Name:	PICC placement accessory
Classification Name:	Percutaneous, implanted, long-term intravascular Catheter
Product Code:	LJS, 21CFR 880.5970
Class:	II

C. Predicate Devices

K140799 Celerity™ System
K093775 Sapiens ™ Tip Location System
Common Name: PICC placement accessory
Classification Name: Percutaneous, implanted, long-term intravascular Catheter
Product Code: LJS, 21CFR 880.5970
Class: II

D. Device Description

The Celerity System includes the Celerity Monitor/Software, ECG Patient Cable, Remote Control Cable, Battery, Power Supply Cord and ECG Clip Cable (alligator clip). Procedural accessories including ECG Snap Leads, Surface Electrodes, Cable Cover and Prep Pads are provided as a convenience for the clinician.

E. Intended Use

The Celerity System is intended to provide real time tip location information of a central venous catheter by utilization of ECG to observe

P-wave changes as the tip approaches the right atrium of the heart via the superior vena cava.

F. Indications for Use

The Celerity System is indicated for the positioning of Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. The Celerity System is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

Note: In general, devices that utilize ECG technique to observe P-wave are limited, but not contraindicated, for patients where cardiac rhythms may change presentation of the P-Wave:
-Atrial fibrillation
-Atrial flutter
-Severe tachycardia
-Pacemaker-driven rhythm
-Chronic obstructive pulmonary disease (COPD)

Such patients are easily identified prior to PICC insertion. Use of an additional confirmation method is necessary to confirm catheter tip location.

G. Technological Characteristics

Technological Characteristics of the subject Celerity are equivalent with respect to the basic system design and function to that of the predicate device. The differences between the predicate and proposed devices do not raise new questions of safety or effectiveness.

H. Safety and Performance

The results of Design Verification and Validation activities were performed in accordance with Design Control requirements per 21 CFR 820.30 and demonstrate that the subject Celerity System meets predetermined performance specifications.

The performance evaluation plan included testing per the following recognized standards to assess conformance to IEC 60601 (3rd Edition).

IEC 60601-1	Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC 60601-1-2	Medical Electrical Equipment – Part 2: General Requirements for Basic Safety and Essential Performance – Collateral Standard Electro Magnetic Compatibility – Requirements and Test

Human Factors Evaluation - Simulated Use Testing alternate to chest x-ray and fluoroscopy:

Simulated Use / Human Factors Testing has been conducted to evaluate the application of the Celerity electrocardiogram (ECG)-Based Tip Confirmation System (i.e., Celerity System) when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. The use related events noted in the studies have been adequately reviewed and addressed in order to ensure the safe, effective use of the device as an alternate to x-ray techniques for confirmation of tip location of PICC. Based on the content of the proposed Celerity System's Risk Analysis / Use and Design FMEAs, and the content of the Instructions for Use, the Celerity System has demonstrated its suitability for its intended purpose.

I. Substantial Equivalence Conclusion

The proposed device is determined to be substantially equivalent to the predicate device based on:

- The Intended Use and Indications for Use
- Operating principles/technology
- Results of safety and performance testing
- Responses to questions posed in FDA 510(k) "Substantial Equivalence" Decision-Making Flowchart