October 26, 2017

Medical Components, Inc. (dba Medcomp®)
Colton Muraira
Regulatory Affairs
1499 Delp Dr.
Harleysville, Pennsylvania 19438

Re: K171931
Trade/Device Name: Celerity™ ECG Cable Accessory Pack
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: September 15, 2017
Received: September 26, 2017

Dear Colton Muraira:

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 (DICE) 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 (DICE) 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,

Tina Kiang, Ph.D.
Acting 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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K171931

Device Name
Celerity ECG Cable Accessory Pack

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)*

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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K171931 510(K) SUMMARY

Manufacturer's Name:	Medical Components, Inc. (dba Medcomp®) 1499 Delp Drive Harleysville, PA 19438
Corresponding Official:	Colton Muraira Regulatory: North America and EU
Telephone Number:	(215) 256-4201, x 2285
Email:	CMuraira@Medcompnet.com
Preparation Date:	October 23, 2017
Trade Name:	Celerity™ ECG Cable Accessory Pack
Common or Usual Name:	PICC Placement Accessory
Regulation Name:	Percutaneous, implanted, long-term intravascular catheter
Regulation Number:	21 CFR 880.5970
Product Code:	LJS
Device Class:	Class II
Primary Predicate Device:	K142889 - AngioDynamics Inc. Celerity™ PICC Tip Confirmation System

Device Description:

The Celerity™ ECG Cable Accessory Pack consists of a sterile remote cover and a specialized alligator PICC clip. The Celerity™ ECG Cable Accessory Pack is designed to be used in conjunction with the Celerity™ System to provide a continuous display of electrocardiograph waveforms to guide placement of peripherally-inserted central catheters in the patient's right atrium of the heart.

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; 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 method is necessary to confirm catheter tip location.

Substantial Equivalence Discussion

The subject device is an accessory pack to the Celerity System. The subject device accessory pack consists of a sterile remote cover and a specialized alligator PICC clip. Both devices use changes in cardiac electrical activity to provide real-time catheter tip location.

Celerity™ ECG Cable Accessory Pack has been compared to the cleared "Celerity™ PICC Tip Confirmation System" (510(k)# K142889) as a reference for substantial equivalence. A table comparing the two devices is provided as follow:

Attribute	Subject Device – K171931: Celerity ECG Cable Accessory Pack	Predicate Device – K142889 : Celerity PICC Tip Confirmation System	Comparison
510(k) Holder	Medcomp, Inc	AngioDynamics	N/A
Design	The Celerity ECG Cable Accessory Pack is designed to be used in conjunction with the Celerity™ System to provide a continuous display of electrocardiograph [ECG] waveforms to guide placement of peripherally-inserted central catheters [PICC] in the patient's right atrium of the heart. **Sterile remote cover:** covers a sufficient length of the remote control cable to provide a sterile barrier capable of being pierced by the remote control PICC connector. **Sterile PICC Clip Connector:**	The Celerity PICC Tip Confirmation System is an accessory to peripherally-inserted central catheters (PICC). It aids a clinician in placing PICC optimally, in the superior vena cava near the entrance to the right atrium of the heart.	Components Same

	Capable of conducting an ECG signal from the PICC stylet to the Celerity remote control.		
Intended use	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.	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.	Same
Indications for use	The Celerity ECG Cable Accessory Pack 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 method is necessary to confirm catheter tip location.	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 method is necessary to confirm catheter tip location.	Same

Target Population	Adults (18 years or older)	Adults (18 years or older)	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Materials	**ECG Clip Cable**: nickel plated steel with a white PVC insulator. The audio connector consists of a nylon and polyethylene insulator and gold or nickel plated contacts **Remote Cover:** latex-free polyethylene	**ECG Clip Cable**: nickel plated steel with a white PVC insulator. The audio connector consists of a nylon and polyethylene insulator and gold or nickel plated contacts **Remote Cover:** latex-free polyethylene	Same

The indications for use statement and the intended use of the subject device are identical to the predicate device. The differences between the subject device and the predicate device are:

1. Proposed device is an accessory pack containing separate components to be used with the predicate Celerity System, which already contains stated components.
2. Different manufacturer of the ECG Clip Cable and Remote Cover

Based on the aforementioned modifications to the subject device, the subject device does not raise different types of safety and effectiveness questions when compared to the predicate device.

Bench/Performance/Non-Clinical Testing

The following testing was conducted to demonstrate substantial equivalence of the Celerity™ ECG Cable Accessory Pack to the predicate devices:

Item	Test Name
1	Alligator Clips – 1 year accelerated aging
2	Alligator Clips – 3 year accelerated aging
3	Equipment Interaction of Alligator Clips, ECG Electrodes, and ECG Snap Leads
4	Probe Cover – 1 year accelerated aging
5	Celerity Accessory Pack – 1 year accelerated aging
6	Celerity Accessory Pack – 3 year accelerated aging
7	Celerity Accessory Packs – ISTA 2A Shipping Test

Biocompatibility
The subject device is non-patient contacting and therefore, biocompatibility testing is not applicable.

Conclusion
The modifications to the subject device include the change of the manufacture of the ECG Clip Cable and the Remote Cover and the packaging of the ECG Clip Cable and Remote Cover as an accessory pack. The modifications do not raise new or different questions of safety and effectiveness and are supported by non-clinical testing.

The Celerity ECG Cable Accessory Pack is substantially equivalent to the Celerity PICC Tip Confirmation System cleared under K142889.