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

April 24, 2015

Medcomp
Ms. Courtney Nix
Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K143238
Trade/Device Name: C3 Wave
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: March 6, 2015
Received: March 10, 2015

Dear Ms. Nix:

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Tina Kiang -S

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

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)*
K143238

Device Name
C3 Wave

Indications for Use *(Describe)*
The C3 Wave System is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgement and established hospital protocol (e.g., Chest X-Ray, Fluoroscopy). Note: Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P wave: atrial fibrillation,atrial flutter, severe tachycardia, pacemaker driven rhythm, and cronic obstructive pulmonary disease (COPD).
Such patients are easily identified prior to PICC insertion. Use of 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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A. Submitter Information:

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Contact: Courtney Nix
Cnix@medcompnet.com
Regulatory Associate

Date Prepared: 11/11/2014

B. Trade Name: C3 Wave

Common Name: PICC placement accessory
Classification Name: Long Term Intravascular Catheter (80 LJS)
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section: 21 CFR 880.5970
Class: II

C. Predicate Devices: K140799 Medcomp, Celerity™ System

D. Device Description:

The C3 Wave system includes the iPad® monitor running the mobile application software, the C3 hub (a battery and power supply cord for the hub), a remote control, and an ECG clip cable (alligator clip). Procedural accessories include the ECG snap leads, ECG patient cable, ECG electrodes, remote cover, and prep pads which are provided as a convenience to the clinician.

E. Intended Use:

The C3 Wave 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 C3 Wave System is indicated for use as a supplemental aid in positioning for Peripherally Inserted Central Catheters (PICC) in adult patients. It provides real-time catheter tip location information by using the patient's cardiac electrical activity. Confirmation of tip placement should be verified according to clinical judgement and established hospital protocol (e.g., Chest X-Ray, Fluoroscopy). Note: Limiting, but not contraindicated, situations for this technique are patients where cardiac rhythms may change presentation of the P wave: atrial fibrillation,atrial flutter, severe tachycardia, pacemaker driven rhythm, and cronic obstructive pulmonary disease (COPD).
Such patients are easily identified prior to PICC insertion. Use of additional confirmation method is necessary to confirm catheter tip location.

G. Comparison to Predicate Devices:

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The C3 Wave system is substantially equivalent to the predicate device in terms of intended use, indication for use, anatomical location, basic design, performance, and labeling.

The difference between the C3 Wave system and the predicate device is in the use of Bluetooth® technology to digitally transfer the ECG waveform to the mobile application running on the iPad® monitor, and also the use of Bluetooth® technology in the remote control which allows the clinician to control the system without breaking the sterile field. The use of Bluetooth® technology eliminates the need to have cables running from the patient to the monitor and improves patient comfort.

H. **Performance Testing:**

Design verification and validation activities were performed in accordance with Design Control requirements per 21 CFR 820.30 and demonstrate that the subject C3 Wave system meets predetermined performance specifications.

The performance evaluation plan included testing per the following recognized standards to assess conformance to IEC 60601-1 (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

I. **Biocompatibility:**

C3 Wave patient contact is limited to the ECG cables. The C3 hub can have limited patient contact if the clinician places the hub on the patient's chest, however the hub can perform the exact same function if placed beside the patient therefore having no patient contact. As a result, biocompatibility testing was conducted on the C3 Wave hub and ECG cables (ECG Alligator Clip and Power Supply Cable) according to ISO 10993-1. The following test results demonstrate that the material used meets ISO 10993 requirements for an external communicating device with circulating blood path:

CYTOTOXICITY:

A: Cytotoxicity Test. Neutral Red Uptake 4 concentration- ISO- Passed- 14-03214-N1

SENSITIZATION:

B: Kligman Maximization – 2 extracts – Passed - Report -14-02840-G2

IRRITATION:

C: ISO Intracutaneous Injection – 2 extracts – Passed – 14-02840-G4

SYSTEMIC TOXICITY:

D: ISO Rabbit Pyrogen (material mediated) – Passed – Report- 14-02840-G5

CHEMICAL CHARACTERIZATION:

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E: Chemical Characterization test performed on the C3 Wave Hub and results were as expected.

J. **Technological Characteristics:**

Technological Characteristics of the C3 Wave system are equivalent to the predicate device with respect to the basic system design but differ in the technology employed to accomplish the same adjunct function. Even with the technology differences between the predicate and proposed devices, no new questions of effectiveness are raised.

K. **Summary of Substantial Equivalence:**

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

- The Intended Use
- Indications for Use
- Basic system design
- Operating principle
- Results of performance testing