December 6, 2017

Medical Components, Inc (dba Medcomp)
Courtney Nix
Regulatory Affairs Manager, North American and Europe
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K170934
Trade/Device Name: C3 Wave System
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: Class II
Product Code: LJS
Dated: October 27, 2017
Received: November 6, 2017

Dear Courtney 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.

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.

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,

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

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)*
K170934

Device Name
C3 Wave System

Indications for Use *(Describe)*
The C3 Wave System is indicated for use in the positioning of Peripherally Inserted Central Catheters (PICC). The C3 Wave provides real-time catheter tip location information by displaying changes in the patient's cardiac electrical activity. The C3 Wave is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.
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
-Chronic obstructive pulmonary disease (COPD)
Such patients are easily identified prior to PICC insertion. Use of additional 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary: K170934

A. Submitter Information:

Submitter:	Medcomp® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x 2285 Fax: (215) 256-9191
Registration Number:	2518902
Contact:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager: North America and EU
Date Prepared:	November 28, 2017

B. Proposed or Subject Device Information:

Trade Name:	C3 Wave System
Device:	Catheter, intravascular, Therapeutic Long-Term Greater Than 30 Days
Product Code:	LJS
Regulation Description:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

C. Predicate Device Information:

510(k) Number:	K143238
510(k) Holder:	Medcomp®
Trade Name:	C3 Wave System
Device:	Catheter, intravascular, Therapeutic Long-Term Greater Than 30 Days
Product Code:	LJS

Regulation Description:	Percutaneous, implanted, long-term intravascular catheter
C.F.R. Section:	880.5970
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

E. Purpose for Submission:

The primary purpose of this submission is to revise the indications for use for the C3 Wave System. The indications currently included, cleared by C3 Wave System K143238, "Confirmation of tip placement should be verified according to clinical judgement and established hospital protocol (e.g., Chest X-Ray, Fluoroscopy)." The proposed indications will revise this statement to read "for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients."

The proposed C3 Wave System is equivalent to the cleared C3 Wave System, K143238, in device design, materials and materials. The changes to the cleared device include the hardware to the hub portion of the system, software, and the indications for use.

F. Device Description:

C3 Wave is designed to provide a continuous display of electrocardiograph [ECG] waveform to be used as a guide in placement of peripherally-inserted central catheters [PICC] in the lower third of the Superior Vena Cava [SVC] of a patient. The principle for operation of this system uses three ECG leads placed on the patient's chest and generates a third ECG lead by switching from RA to PICC stylet. The ECG waveform is wirelessly transmitted to a tablet which allows the operator to view and record changes to the ECG waveform as the tip of the catheter approaches the heart. As the PICC catheter approaches the atrium of the heart, the P wave in the ECG waveform shows substantial changes. This system is designed to aid the visualization of changes in P wave amplitude.

The C3 Wave system must only be operated by a skilled nurse, physician, or trained medical professional who has been qualified in placement of PICC's and trained in the proper use of this device.

G. Indications for Use:

The C3 Wave System is indicated for use in the positioning of Peripherally Inserted Central Catheters (PICC). The C3 Wave provides real-time catheter tip location information by displaying changes in the patient's cardiac electrical activity. The C3 Wave is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients.

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

-Chronic obstructive pulmonary disease (COPD)

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

H. Intended Use:

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.

I. Comparison to Predicate Device:

The C3 Wave system is substantially equivalent to the predicate device.

510(K) Summary: Comparison Table

Device	Proposed Device: The C3 Wave System K170934	Predicate Device: The C3 Wave System (K143238)	Substantially Equivalent Comparison
Indications for Use	The C3 Wave System is indicated for use in the positioning of Peripherally Inserted Central Catheters (PICC). The C3 Wave provides real-time catheter tip location information by displaying changes in the patient's cardiac electrical activity. The C3 Wave is indicated for use as an alternative method to chest X-ray or fluoroscopy confirmation of PICC tip placement in adult patients. **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	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 XRay, 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 chronic	The subject device is indicated as an alternative method to chest x-ray or fluoroscopy confirmation of PICC tip placement in adult patients, subject to the noted limitations. The differences between the subject and predicate device indications for use do not raise different questions of safety and effectiveness. Performance data was provided to verify the design

	-Chronic obstructive pulmonary disease (COPD) Such patients are easily identified prior to PICC insertion. Use of additional method is necessary to confirm catheter tip location.	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.	and labeling adequately support the revised indications for use.
User/Setting	Prescription Use – Hospital/Clinical Setting	Prescription Use – Hospital/Clinical Setting	Equivalent
Patient/User Interface	iPad	iPad	Equivalent
System	iPad, C3 Wave Hub, ECG Leads, C3 Wave Remote	iPad, C3 Wave Hub, ECG Leads, C3 Wave Remote	Equivalent
Sterilization Method	Sterile Accessory Packs – EO	Sterile Accessory Packs – EO	Equivalent
Energy Source	Mains power (battery backed)	Mains power (battery backed)	Equivalent
EMC & Electrical Safety	IEC 60601-1 IEC 60601-1-2	IEC 60601-1 IEC 60601-1-2	Equivalent

ATTRIBUTE	**C3 Wave (Proposed Device)**	**C3 Wave System (K143238)**
Operating Principle/Technology:	The C3 Wave system consists of an iPad® monitor, a C3 hub, and remote control. First, the hub, which can be placed on the patient's chest, collects the ECG signal from the surface ECG (via ECG chest pad electrode leads) and the intravascular ECG (lead connected to the catheter stylet). Next, the waveform is sent wirelessly by Bluetooth™ technology from the hub to the mobile application. Then, the C3 mobile application, installed on an iPad®, displays the ECG waveform. Hence, the medical professional can monitor the location of the PICC catheter through the ECG waveform and, specifically, monitor the P-wave shape and amplitude which indicates tip position relative to the sinoatrial node. Further, sterility can be maintained during the entire	The C3 Wave system consists of an iPad® monitor, a C3 hub, and remote control. First, the hub, which can be placed on the patient's chest, collects the ECG signal from the surface ECG (via ECG chest pad electrode leads) and the intravascular ECG (lead connected to the catheter stylet). Next, the waveform is sent wirelessly by Bluetooth™ technology from the hub to the mobile application. Then, the C3 mobile application, installed on an iPad®, displays the ECG waveform. Hence, the medical professional can monitor the location of the PICC catheter through the ECG waveform and, specifically, monitor the P-wave shape and amplitude which indicates tip position relative to the sinoatrial node. Further, sterility can be maintained during the entire process as the C3 Wave

	process as the C3 Wave system is controlled using a remote control.	system is controlled using a remote control.

The proposed C3 Wave System is equivalent to the cleared C3 Wave System, K143238, in device design, materials and materials. The changes to the proposed device from the predicate are in the hardware to the hub portion of the system, software and the expanded indications for use.

Through performance bench testing, the subject device has demonstrated that it is substantially equivalent to the predicate.

J. Non-Clinical Performance Testing

Standards	Performance Testing
IEC 60601-1:2006+A12:2014 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	IEC 60601-1 Test Report (E468297-D1-IT-1)
IEC 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests	IEC 60601-1-2 Test Report (R-2642P)
IEC 62304:2006 Medical device software — Software life cycle processes	IEC 62304 Test Report Equipment Interaction C3 Wave Remote – Updated Firmware C3 Wave Application Software – Equipment Interaction *Software Driven Warnings" C3 Wave – Equipment Interaction (C3 Wave Application iPad Software) Lextech - Medcomp functionality checklist VPI - Hub firmware test VPI - Remote firmware test
ISTA-2A Partial simulation performance test procedure	Non-Sterile C3 Wave Accessory Pack- ECG Electrodes Test Summary

	C3 Wave Navigation System w/ iPad – ISTA-2A Shipping Test Summary
ISTA-1A Non-simulation integrity performance test procedure	C3 Wave Hub – ISTA-1A Shipping Test
IEC 62133:2013 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	IEC 62133 CB Test Certificate (4307556.50)
47 CFR Part 15, Subpart C Intentional Radiators	Bluetooth Low Energy Certification Test Report (10463456A) Bluetooth Low Energy Certification Test Report (10463456B) EN 300 328 V1.8.1 Certification Test Report (14L18625-E1)(Remote) EN 300 328 V1.8.1 Certification Test Report (14L18625-E2)(Hub)
RSS-210 License-Exempt Radio Apparatus: Category I Equipment	Bluetooth Low Energy Certification Test Report (10463456A) Bluetooth Low Energy Certification Test Report (10463456B) EN 300 328 V1.8.1 Certification Test Report (14L18625-E1) EN 300 328 V1.8.1 Certification Test Report (14L18625-E2)
ETSI EN 300 328 V1.8.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive	EN 300 328 V1.8.1 Certification Test Report (14L18625-E1) EN 300 328 V1.8.1 Certification Test Report (14L18625-E2))
ETSI EN 301 489-17 V2.2.1 Electromagnetic compatibility and Radio spectrum Matters (ERM); ElectroMagnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems	Bluetooth Low Energy Certification Test Report (10463456A) Bluetooth Low Energy Certification Test Report (10463456B)

Bluetooth 4.1	Low Energy RF PHY Test Specification (TS): Test Suite Structure (TSS) and Test Purposes (TP) RF-PHY.TS.4.1.0 (UL-BQT-RP10522414JD01A V2.0) (Hub) Low Energy RF PHY Test Specification (TS): Test Suite Structure (TSS) and Test Purposes (TP) RF-PHY.TS.4.1.0 UL-BQT-RP10522414JD02A V2.0 (Remote)

In addition to demonstrating performance in accordance with these standards, the submission contained information recommended in FDA guidance documents for software and cybersecurity:

- Content of Premarket Submissions for Software Contained in Medical Devices.
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

The current released version of the C3 Wave app is 2.0.3. The current released remote firmware is version 16. The current released hub firmware is version 39.

Clinical and Human Factors Testing

Clinical and human factors studies were collected/performed to evaluate the C3 Wave System.

Clinical Study

Clinical Surveys were completed to demonstrate that various PICC line nurses of different years of experience can successfully insert the PICC Line based on their ability to read the ECG display on the iPad

- Objective: To demonstrate clinical acceptance between the MedComp C3 Wave System ECG Tip Confirmation System positioning results and traditional portable chest xray in determining proper distal tip location during a PICC procedure.
- Methods: A total of 303 PICCs were to be placed at two healthcare facilities using the C3 Wave System ECG Tip Confirmation System in accordance with the instructions for use. A subsequent portable chest x-ray was to be obtained, with the patient position similar of PICC placement, to ascertain acceptable tip location of PICC. The clinician was to complete an electronic survey document to capture specific data points within each procedure including insertion related

assessments and final catheter functionality questions referred to as the Bundle Protocol.

Outcome: The C3 Wave System has demonstrated a 98% success rate when the Bundle Protocol Parameters were met.

Human Factors

Human Factors Testing has been conducted to evaluate the application of the C3 Wave System when used to confirm PICC tip position as an alternative method to chest X-ray or fluoroscopy confirmation. Participants in the study were representative of the population who place PICC lines in the clinical environment where the product is intended to be used, e.g., hospital wards, acute care centers, extended care centers, alternate care centers, and outpatient clinics. Clinicians with experience in the placement of PICC lines were recruited for the study. No critical task failures were observed in the study.

K. Summary/Conclusion of Substantial Equivalence:

In conclusion, the proposed device, C3 Wave System, is equivalent to the predicate device, C3 Wave System (K143238).