April 12, 2018

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

Re: K180567
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: March 12, 2018
Received: March 15, 2018

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180567

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 contrindicated, 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.

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K180567 510(k) SUMMARY Special 510K

A. Submitter Information:

Submitter:	Medical Components Inc. (dba Medcomp®) 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 x 2285 Fax: (215) 256-9191
Registration Number:	2518902
Contact Person:	Courtney Nix Regulatory Affairs Manager, North America and Europe
Date of Preparation:	03/02/2018

B. Subject Device

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

510(k) Number:	K170934
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

D. Subject of Submission:

The purpose of this submission is to expand the accessory packs offerings for the C3 Wave System. The K170394 clearance includes three accessory packs. The submission is to add an accessory code that contains a large drape. As a result, the packaging system had to be revised to a larger header bag. All testing was completed and is the subject of this submission.

E. 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.

F. 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.

G. **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.

H. Comparison to Predicate Devices:

Table 6.1: 510(K) Summary: Design Comparison Matrix

Device	**Proposed Device:** C3 Wave System (MRC3RD004)	**Predicate Device:** C3 Wave System (MRC3RD000)	**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 -Chronic obstructive pulmonary disease (COPD) Such patients are easily identified prior	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	Unchanged

	to PICC insertion. Use of additional method is necessary to confirm catheter tip location.	to PICC insertion. Use of additional method is necessary to confirm catheter tip location.	
User/Setting	Prescription Use – Hospital/Clinical Setting	Prescription Use – Hospital/Clinical Setting	Unchanged
Patient/User Interface	iPad	iPad	Unchanged
System	iPad, C3 Wave Hub, ECG Leads, C3 Wave Remote	iPad, C3 Wave Hub, ECG Leads, C3 Wave Remote	Unchanged
Overall System Components (incl. Accessory Packs)	iPad, iPad Case, Remote, Remote Battery, Hub, Hub Battery, Hub Power Supply, Leads, Base, ECG Clip Cable, Remote Cover, Electrodes, Skip Prep, Drape	iPad, iPad Case, Remote, Remote Battery, Hub, Hub Battery, Hub Power Supply, Leads, Base, ECG Clip Cable, Remote Cover, Electrodes, Skip Prep, Drape	Equivalent; Change to Dimension of Drape
Sterile Accessory Pack Components	ECG Clip Cable, Remote Cover, and Drape	ECG Clip Cable, Remote Cover, and Drape	Equivalent; Change to Dimension of Drape
Drape Dimensions	100” x 86”	45” x 40”	Equivalent; Change to Dimension of Drape
Sterilization Method	Sterile Accessory Packs – EO	Sterile Accessory Packs – EO	Unchanged
Packaging Systems	12.250”x18.500” Tyvek Headerbag CSR wrapped kit placed inside a Tyvek /LLDPE headerbag and shipped within a corrugated shipping carton	17.500”x10.750” Tyvek Headerbag CSR wrapped kit placed inside a Tyvek /LLDPE headerbag and shipped within a corrugated shipping carton.	Equivalent; Change to Dimension of Headerbag to accommodate larger drape
Testing (Accessory Packs)	ISTA 2A, Endotoxin, EO Residuals, and LAL	ISTA 2A, Endotoxin, EO Residuals, and LAL	Unchanged

I. Non-Clinical Testing

The Following non-clinical testing was completed on the modified accessory pack (larger drape and headerbag). Testing was performed as a result of the risk assessment and design control activities based on the subject device modifications from the cleared predicate.

Biocompatibility:

Biocompatibility was performed for the device modifications per ISO 10993-1 for a skin contacting surface device, with limited exposure (i.e. less than 24 hours).

CYTOTOXICITY:
ISO 10993-5: 2009; *Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity*

SENSITIZATION:
ISO 10993-10; *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*

IRRITATION:
ISO 10993-10; *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*

Sterilization testing on the modified subject device:

The sterilization cycle was developed using the Overkill Approach defined in ANSI/AAMI/ISO 11135-1: 2014, Annex B. The Microbiological Performance Qualification was performed in accordance with ANSI/AAMI/ISO 11135-1: 2014, section 9.4.2 and the Physical Performance Qualification was performed in accordance with section 9.4.3.

The residuals for C3 ECG Cable Accessory Pack (MRC3RD004) were in accordance with AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals, the maximum level is 4/mg/device.

The packaging integrity of the pouch seal was validated with a dye test per ASTM F 1929-15.

The strength of the packaging seal was validated with a compressed air burst test per ASTM F1140/F1140M-13.

J. Summary of Substantial Equivalence:

Based on the indications for use, design, and performance testing results, the modified subject device raises no new questions of safety or effectiveness compared to the predicate device and is substantially equivalent to the predicate device, C3 Wave System (K170934).