

Section 30.0

Disclosures

Performance Testing – Clinical Studies

N/A - Clinical studies were not deemed necessary for C3 Wave System Accessory Pack.

Performance Testing – Animal

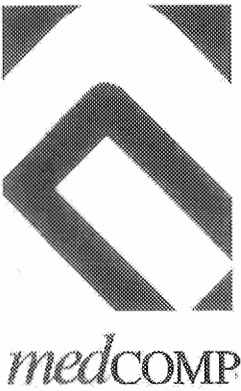
N/A - There was no animal performance testing completed for the C3 Wave System Accessory Pack.

Financial Certification or Disclosure Statement

N/A - No clinical studies have been submitted requiring financial certification or a disclosure statement.

Class III Summary and Certification

N/A - The C3 Wave System Accessory Pack is not a Class III device, therefore, a class III summary and certification is not required.



1499 Delp Drive
Harleysville, PA 19438
Tel: 215-256-4201
Fax: 215-256-1787
www.medcompnet.com

(b)(4)

Bacterial Endotoxin Suitability Test (BET) / Testing for Interfering Factors
Kinetic-QCL Test Method

Procedure Reference: (b)(4)

(b)(4) WO#: (b)(4) Page 1 of 1
Date Received: 16JUN2017 Date Tested: 19JUN2017

Customer:	Medcomp 1499 Delp Drive Harleysville, PA 19438	Product:	C3 Wave ECG Cable Accessory Pack
		Cat / Part #:	(b)(4)
		Lot #:	
		Load #:	

(b)(4)

(b)(4) Testing

(b)(4) Testing



U.S. FOOD & DRUG
ADMINISTRATION

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 -
S

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

Indications for Use

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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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).



Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

- C3 Wave™ System Instructions for Use: These instructions are for use in conjunction with the C3 Wave™ System Owner's Manual.

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 disorder (COPD)

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

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.

CONTRAINDICATIONS

- There are no contraindications associated with the C3 Wave™ system. Consult catheter Instructions for Use for Possible Catheter Contraindications.

WARNINGS

- The C3 Wave™ system works with the normal sinus rhythm of the heart. Do not rely on ECG signal detection for catheter tip positioning when interpretation of the external or intravascular ECG P-wave is difficult.

For example, when:

- P-wave is not present
- P-wave is not identifiable
- P-wave is intermittent

- Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use.

- All components in the accessory pack are single use items. Do not reuse or reprocess.

- Monitor catheter tip placement during insertion procedure and verify catheter tip location placement using your institutions' guidelines.

- Failure to verify catheter placement may result in serious trauma or fatal complications.

- Inspect package and product prior to use to verify that no damage has occurred during shipping.

- Reuse or reprocessing may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death.

- Reuse or reprocessing may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another.

- Contamination of the device may lead to injury, illness or death of the patient.
- After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

- Do not use the hub when plugged in.

- No additional snapshots should be taken after the "maximum P-wave" snapshot.

PRECAUTIONS

- NEVER cut the stylet or stiffening wire.

- Discard Biohazard according to facility protocol.

- Never use excessive force to advance/remove the stylet as it may damage the device or result in patient injury.

PROCEDURAL INSTRUCTIONS

1. Prepare For Use of C3 Wave™ System.

- Prior to use, the clinician must read and understand all labeling and instructions provided with the C3 Wave™ devices (including C3 Wave™ Owner's Manual).

- Follow manufacturer's instructions provided with all accessory devices.

2. Identify Catheter Insertion Site.

- Refer to catheter manufacturer's Instructions for Use.
- Mark planned insertion site on patient's arm.

3. Determine External Surface Measurement.

- For central venous placement, the recommended target tip location is the lower 1/3 of the Superior Vena Cava (SVC)/right atrial junction.
- Use the following guidelines during patient positioning and measurement.

- When possible, ensure patient has both shoulders in contact with the bed. Patient should not be rotated during measurement procedure.

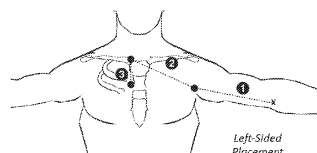
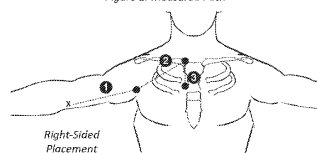
- When possible, measure directly on patient's skin. Measuring over clothing, bedding, existing ECG adhesive electrodes, wound dressings, or other personal and/or medical equipment may introduce measurement error.

Note: External surface measurement can never exactly duplicate the internal venous anatomy.

- Measure path from the planned insertion site using the following external landmarks:

- Insertion site to axillary crease.

Figure 1. Measured Path



- Axillary crease to right clavicular head. Measure to the right clavicular head for both left and right-sided placements.

- Right clavicular head to the right sternal border at the third intercostal space.

Note: The first intercostals space may be difficult to palpate due to its proximity to the clavicle.

- Record External Surface Measurement _____ cm

PREPARE ELECTRODES

- Attach ECG Patient Hub to the three ECG snap leads.

- Prepare and attach ECG adhesive electrodes per the following steps.

Caution: ECG adhesive electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected or inflamed areas). For best results use the supplied ECG adhesive electrodes.

- Attach ECG adhesive electrodes to all three ECG snap leads.
- Remove backing and press ECG adhesive electrodes firmly onto skin at the specified locations

Warning: Place ECG adhesive electrodes carefully at locations indicated in these Instructions for Use and ensure good skin-electrode contact. Failure to do so may cause unstable ECG waveforms and/or ECG waveforms that are not described in these Instructions for Use.

- Black ECG snap lead/adhesive electrode on the patient's left upper chest.
- Red ECG snap lead/adhesive electrode on patient's lower left side, inferior to the umbilicus and laterally along the mid-axillary line.

Caution: Placement of red electrode outside of this region may result in reduced ECG performance.

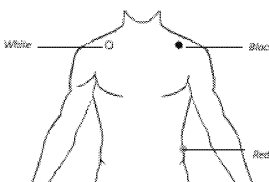


Figure 2. Electrode Locations

- White ECG snap lead/ECG adhesive electrode on patient's right upper chest.

Caution: If skin irritation occurs, discontinue ECG adhesive electrode use immediately.

- Evaluate baseline ECG waveform.

- With the C3 Wave™ system running in Surface Mode, the external ECG waveform should be visible and stable at this time.

- Verify that the P-wave is present, identifiable and consistent on the main screen of the C3 Wave™ system.

- Obtain snapshot of baseline ECG.
- Enter surface external measurement. (See Step 3-D).

4. Prepare Sterile Field

- Set up sterile field according to catheter Instructions for Use and institutional protocol.

- Cover the Remote Control with sterile Cover (provided in the C3 Wave™ ECG Cable Accessory Pack).

5. Prepare Catheter

- Follow catheter manufacturer's Instructions for Use and institutional protocol.

- Trim catheter to length per the following steps.

- Determine the desired indwelling catheter length based on clinician measurement technique and experience, typically this is the measurement from the zero mark on the catheter to the predetermined catheter external Surface Measurement, See Step 3-D.

- To ensure adequate catheter length to reach maximum P-wave amplitude, it is recommended that the trimmed catheter length is 2cm more than the external/surface measurement.

- Retract the stylet until it is well behind the targeted catheter cut location. Do not entirely remove the stylet from the catheter.

Note: Catheter depth markings are generally in centimeters – refer to catheter labeling.

- Follow catheter manufacturer's Instructions for Use for trimming.

Caution: NEVER cut the stylet or stiffening wire.

- Inspect cut surface to ensure there is no loose material.

- Ensure stylet tip is intact.

Caution: Never use excessive force to advance/remove the stylet as it may damage the device or result in patient injury.

- Prior to catheter insertion, ensure that the stylet tip is contained within the catheter, but not more than 1 cm from the trimmed end of the catheter, secure stylet within the catheter manufacturer's Instructions.

Warning: Ensure that the stylet tip does not extend beyond the trimmed end of the catheter. Extension of the stylet tip beyond the catheter end combined with kinking and excessive forces may result in vessel damage, stylet damage, difficult removal, stylet tip separation, potential embolism and risk patient injury.

- Attach saline-filled syringe and flush catheter.

- Remove the syringe after flushing.

6. Catheter Insertion

- Perform ultrasound and locate vessel. Follow ultrasound system Instructions for Use.

- Follow catheter Instructions for Use regarding Venous Access and Catheter Insertion.

- Connect the end of the ECG Clip Cable (provided in the ECG Cable Accessory Pack) through the drape window to the ECG patient hub.

Note: C3 Wave™ only works with conductive [metal] stylets.

- Secure the ECG Clip Cable (alligator clamp) to the proximal end of the stylet.

- Place C3 Wave™ System monitor in 'Internal Mode' and insert catheter per manufacturer's Instructions for Use.

- Flush catheter with saline and wait for intravascular ECG waveform to stabilize on monitor screen.

- Verify that the P-wave on the intravascular ECG waveform is present, identifiable, and consistent on monitor screen.

Warning: Do not rely on ECG signal detection for Catheter tip positioning when interpretation of the P-wave is difficult. For example, when:

- P-wave is not present
- P-wave is not identifiable
- P-wave is intermittent

7. Catheter Tip Guidance and Positioning

The following figures show approximate catheter tip positions and representative intravascular ECG waveforms.

Figure 1: No evident P wave change - catheter tip is not in an acceptable position.

Figure 2: P wave at its maximum height - catheter tip is in the lower 1/3 of superior vena cava/right atrial junction.

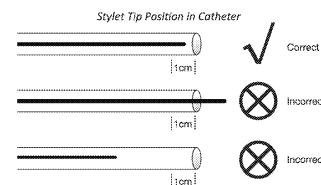
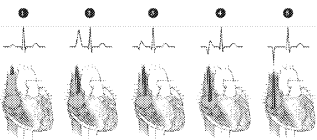


Figure 3: Downward deflection on the leading edge of the P wave - catheter tip is entering the right atrium.

Figure 4: Biphasic P wave – catheter tip is within the right atrium.

Figure 5: Inverted P wave - catheter tip is approaching the right ventricle.



Confirm all Bundle Protocol Parameters have been met.

Catheter Insertion
Catheter advanced to target without resistance?
Stylet removed from catheter without resistance?
Catheter Functionality
Positive/free flowing blood return (all lumens)?
Flushing without resistance (all lumens)?
Objective Assessment
US assessment of internal jugular vein negative for catheter?
EKG tip location agrees with surface measurement (+/- 2cm)?
ECG P Wave Assessment
Initial P wave downward deflection noted and documented?
P wave amplification noted & highest waveform documented?

Warning: If “No” is selected for “Were all parameters met,” you cannot rely solely on the ECG interpretation by C3 Wave™. You must obtain additional confirmation with chest X-ray of fluoroscopy to confirm the PICC tip location.

- A. As the catheter is advanced toward the SVC/Right atrial junction the P-wave height will increase.
- B. Advance Catheter until downward deflection is seen on the leading edge of the P-wave. Select the “snapshot icon” using the Remote Control to save the ECG waveforms.

Note: P-wave may continue to increase in amplitude when initial downward deflection is observed. In this case, adjust catheter tip position to maximum P-wave amplitude with no downward deflection as shown below.

- C. Pull catheter back until maximum P-wave is achieved.
- D. Select the “snapshot” icon using the Remote Control Cable to save the ECG waveforms. Refer to the C3 Wave™ Owners Manual.

Warning: No additional snapshots should be taken after the “maximum P-wave” snapshot.

- E. Verify placement (e.g. chest x-ray or fluoroscopy) prior to releasing the catheter for use if all of the Bundle Protocol Parameters are not met.
- F. Using the C3 Wave™ system, central venous catheter tip location can be documented for the patient's chart. Refer to C3 Wave™ Owner's Manual.

8. Complete PICC Placement Procedure

- A. Follow catheter Instructions for Use and institutional protocol.
- remove the stylet
 - aspirate and flush catheter
 - secure catheter
- B. Remove drapes and ECG adhesive electrodes and discard according to institutional protocol.
- Caution:** ECG Adhesive Electrode may damage the skin if removed carelessly.
- C. Disconnect Patient ECG Hub from ECG Clip Cable.
- D. Dispose of the single use ECG Clip Cable, Remote Cover according to institutional protocol.
- E. Retain the reusable ECG Snap Leads, ECG Patient Hub; Remote Control and clean per institutional protocol.

WARRANTY

Medcomp® WARRANTS THAT THIS PRODUCT WAS MANUFACTURED ACCORDING TO APPLICABLE STANDARDS AND SPECIFICATIONS. PATIENT CONDITION, CLINICAL TREATMENT, AND PRODUCT MAINTENANCE MAY EFFECT THE PERFORMANCE OF THIS PRODUCT. USE OF THIS PRODUCT SHOULD BE IN ACCORDANCE WITH THE INSTRUCTIONS PROVIDED AND AS DIRECTED BY THE PRESCRIBING PHYSICIAN.

Because of continuing product improvement, prices, specifications, and model availability are subject to change without notice. Medcomp® reserves the right to modify its products or contents in accordance with all relevant regulatory requirements.

Medcomp® is a registered trademark of Medical Components, Inc.

C3 Wave™ is a trademark of Medical Components, Inc.

SYMBOL TABLE	
1.5.1	Manufacturer *
1.5.4	Keep Dry *
1.5.5	Upper Limit of Temperature *
1.5.2	Keep Away from Sunlight *
	Rated type CF patient protection.
1.4.4	Caution, consult Accompanying Documents *
1.5.3	Use By Date *
1.4.2	Do Not Re-use *
	On
	Standby
1.2.3	Sterilized Using Ethylene Oxide *
1.2.4	Do Not Use if Package is Damaged *
1.4.1	Consult Instructions for Use*
1.5.3	Date of Manufacture *
1.5.2	Batch/Lot Number *
1.5.6	REF Catalogue Number *
1.5.7	SN Device serial Number *
	Read Accompanying Documents for important safety-related information.

* This symbol is in accordance with ISO 15223-1.

Note: Temperature symbols : "This symbol only applies to kits with drugs".



Medical Components, Inc.
1499 Delp Drive
Harleysville, PA 19438 U.S.A.
Tel:215-256-4201
Fax:215-256-1787
www.medcompnet.com

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional☒ Special☐ AbbreviatedSTANDARD TITLE¹

14-360: AAMI/ ANSI ST72:2011(R), Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing (Sterility)

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐

FDA Recognition number³ #14-360

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

(b)(4)

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? ☒ ☐
If yes, was the guidance document followed in preparation of this 510(k)? ☒ ☐

Title of guidance: Guidance for Industry Pyrogens and Endotoxins Testing: Questions and Answers June 2012

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-360.AAMI/ ANSI ST72:2011/(R), Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 2	SECTION TITLE Normative References	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 3	SECTION TITLE Definitions	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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.* The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASaff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-360: AAMI/ ANSI ST72:2011/(R), Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Quality Management Systems Elements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 5	SECTION TITLE Non-pyrogenic labeling	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 6	SECTION TITLE Selection of product units	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 7	SECTION TITLE Selection of technique	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-360:AAMI/ ANSI ST72:2011/(R), Bacterial Endotoxins - Test Methods, Routine Monitoring, and Alternatives to Batch Testing (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 8	SECTION TITLE Validation of Methodology	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 9	SECTION TITLE Use of Technique	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 10	SECTION TITLE Alternatives to Batch Testing	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
N/A PTM 01 MAR 2018		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional☒ Special☐ AbbreviatedSTANDARD TITLE¹

14-278: AAMI/ ANSI/ ISO 10993-7: 2008(R)2012, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals (Sterility).

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐

FDA Recognition number³ #14-278

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: N/A - No Guidance

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-278: AAMI/ ANSI/ ISO 10993-7: 2008(R)2012, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals (Sterility).		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 2	SECTION TITLE Normative References	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 3	SECTION TITLE Terms and Definitions	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. ♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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.* The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-278: AAMI/ ANSI/ ISO 10993-7: 2008(R)2012, Biological Evaluation of Medical Devices - Part 7: Ethylene Oxide Sterilization Residuals (Sterility).		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Requirements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 5	SECTION TITLE Product Release	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☐ Traditional☒ Special☐ AbbreviatedSTANDARD TITLE ¹

14-452: ISO 11135 Second Edition 2014. Sterilization of Health Care products - ethylene oxide - requirements for the development, validation and routine control of sterilization process for medical devices. (Sterility)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #14-452

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☒ ☐
If yes, was the guidance document followed in preparation of this 510(k)? ☒ ☐

Title of guidance: Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Device

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE: 14-452: ISO 11135 Second Edition 2014, Sterilization of Health Care products - ethylene oxide - requirements for the development, validation and routine control of sterilization process for medical devices. (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 2	SECTION TITLE Normative References	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 3	SECTION TITLE Terms and Definitions	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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.* The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASuff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-452: ISO 11135 Second Edition 2014, Sterilization of Health Care products - ethylene oxide - requirements for the development, validation and routine control of sterilization process for medical devices. (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Quality Management System	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 5	SECTION TITLE Sterilizing agent characterization	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 6	SECTION TITLE Process and Equipment characterization	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 7	SECTION TITLE Product definition	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-452: ISO 11135 Second Edition 2014, Sterilization of Health Care products - ethylene oxide - requirements for the development, validation and routine control of sterilization process for medical devices. (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 8	SECTION TITLE Process Definition	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 9	SECTION TITLE Validation	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 10	SECTION TITLE Routine Monitoring and Control	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 11	SECTION TITLE Product Release from Sterilization	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-452: ISO 11135 Second Edition 2014, Sterilization of Health Care products - ethylene oxide - requirements for the development, validation and routine control of sterilization process for medical devices. (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 12	SECTION TITLE Maintaining Process Effectiveness	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

N/A
JAM 01 MAR 2018

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional☒ Special☐ AbbreviatedSTANDARD TITLE ¹

14-454: ISO 11607-1 First Edition 2006-04-15, Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #14-454

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ ☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: N/A - No Guidance

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
14-454: ISO 11607-1 First Edition 2006-04-15, Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative References	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
N/A

DESCRIPTION
N/A

JUSTIFICATION
N/A

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-454: ISO 11607-1 First Edition 20006-04-15, Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE General Requirements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 5	SECTION TITLE Materials and preformed sterile barrier systems	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 6	SECTION TITLE Design and development requirements for packaging	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 7	SECTION TITLE Information to be provided	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☐ Traditional☒ Special☐ AbbreviatedSTANDARD TITLE ¹

14-455: ISO 11607-2 First Edition 2006-04-15, packaging for terminally sterilized medical devices - part 2: Validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. Sterility

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #14-455

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ ☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: N/A - No guidance

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d]. <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-455: ISO 11607-2 First Edition 2006-04-15, packaging for terminally sterilized medical devices - part 2: Validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. Sterility		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 3	SECTION TITLE Terms and Definitions	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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.* The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE 14-455: ISO 11607-2 First Edition 2006-04-15, packaging for terminally sterilized medical devices - part 2: Validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. Sterility		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE General Requirements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 5	SECTION TITLE Validation of Packaging processes	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 6	SECTION TITLE Packaging system assembly	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
SECTION NUMBER 7	SECTION TITLE Use of reusable sterile barrier systems	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED * N/A		
DESCRIPTION N/A		
JUSTIFICATION N/A		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

14-455: ISO 11607-2 First Edition 2006-04-15, packaging for terminally sterilized medical devices - part 2: Validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. Sterility

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

8

SECTION TITLE

Sterile fluid-path packaging

CONFORMANCE?

☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

N/A

DESCRIPTION

N/A

JUSTIFICATION

N/A

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes☐ No☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes☐ No☐ N/A

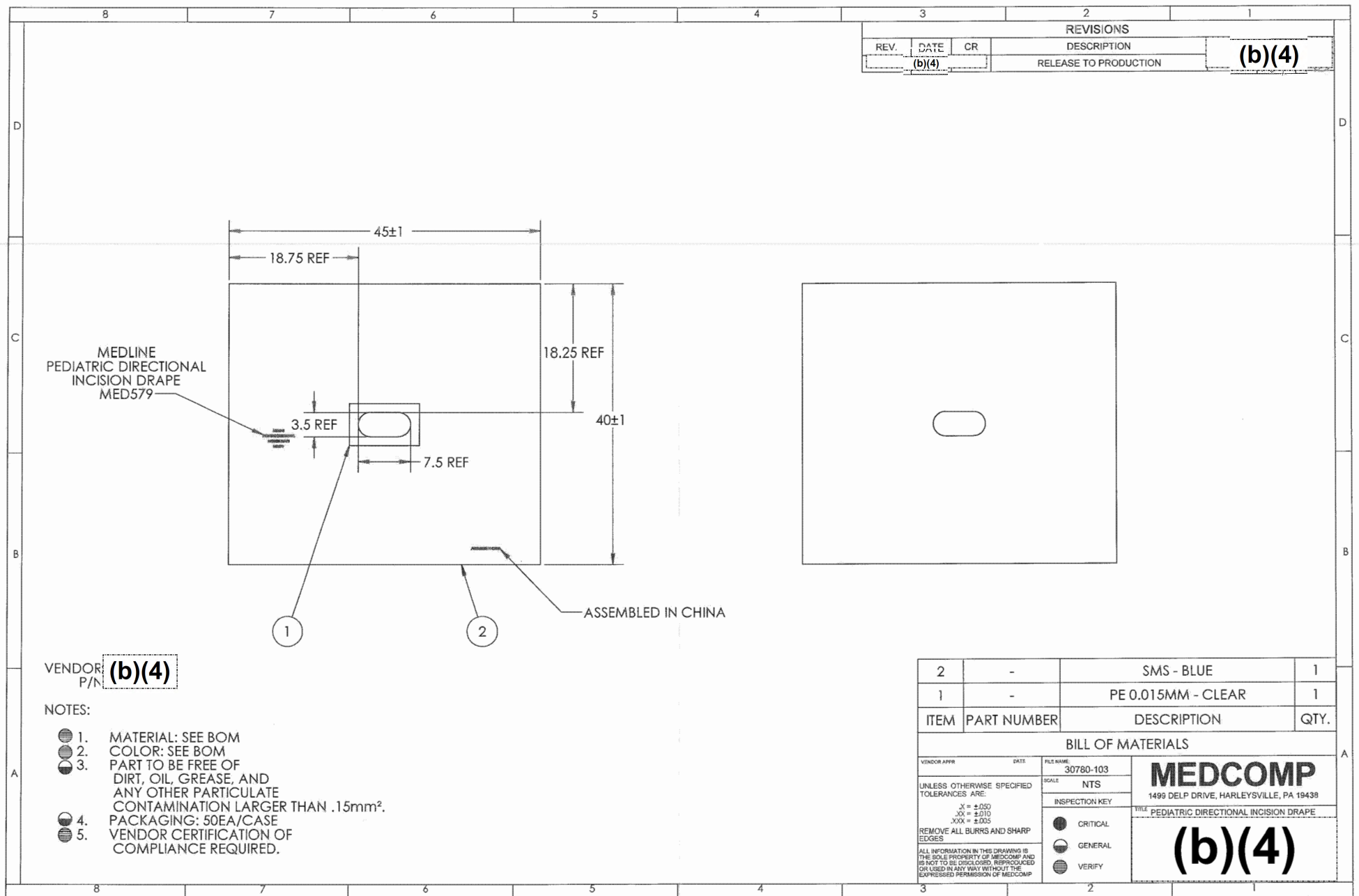
TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.





PRODUCT VERIFICATION/VALIDATION RESULTS
SUMMARY

ORIGINATOR: (b)(4) DATE: 02/23/18

PROJECT NUMBER: (b)(4) STUDY/TEST: VERIFICATION ☐
VALIDATION ☒ V NUMBER: (b)(4)

DEVICE DESCRIPTION: C3 ECG Cable Accessory Pack (MRC3R004) 3 Year Accelerated Aging

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing



PRODUCT VERIFICATION/VALIDATION TEST
PROTOCOL

ORIGINATOR: (b)(4) DATE: 11/7/17

PROJECT NUMBER: (b)(4) STUDY/TEST: VERIFICATION ☐
VALIDATION ☒ V NUMBER: (b)(4)

DEVICE DESCRIPTION: C3 ECG Cable Accessory Pack (MRC3R004) 3 Year Accelerated Aging

DEPARTMENT: ☒ ENGINEERING ☐ COMPLIANCE

TEST/STUDY: ☒ ORIGINAL ☐ AMENDMENT

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Copy

(b)(4)

TEST REPORT

(b)(4)

3-Year (T3) Accelerated Aging for C3 ECG Cable Accessory Pack (MRC3R004)

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Exellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/cs/odhccustomerservice?C=499&I=430&B=433&E=83&E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?C=406&I=430&B=432&E=6555>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

March 16, 2018</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your premarket notification (510(k)) K180567/S001, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Kathleen Fitzgerald.</p>

<p>*** This is a system-generated email notification ***</p>



U.S. FOOD & DRUG
ADMINISTRATION

Build Correspondence

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



Medcomp Label Proof

Proof ID

MRC3RD000-E

Rev

(b)(4)

Catalog Number

MRC3RD000

CR #

(b)(4)

APPROVED

By Kim Deibler at 2:42 pm, 2/2/18

Revision History:

(b)(4)



Medcomp Label Proof

Catalog Code

MRC3RD000

Label Stock P/N

(b)(4)

Placement or Use

Shipping Box Label

CR #

(b)(4)

Proof ID: MRC3RD000-E

Rev: (b)(4)



REF MRC3RD000

C3 WAVE ECG CABLE
ACCESSORY PACK

12 UNITS

LOT

XXXXXXX



USE BY

1111-11-11



Medical Components, Inc. 1499 Delp Drive, Harleysville, PA 19438 U.S.A.
Tel: 215-256-4201 Fax: 215-256-1787 www.medcompnet.com

NOT MADE OR MANUFACTURED WITH NATURAL RUBBER LATEX



(01) 5 0884908 13148 7 (17) 111111 (10) XXXXXXXX

Please consult symbols glossary within the IFU.

MED LABEL REV. A



Medcomp Label Proof

Catalog Code

MRC3RD000

Label Stock P/N

(b)(4)

Placement or Use

Customer Survey Label

CR #

21150

Proof ID: MRC3RD000-E

Rev: (b)(4)

We want your feedback!
Please visit:



<https://www.medcompnet.com/contact/Feedback/>



Medcomp Label Proof

Catalog Code

MRC3RD000

Label Stock P/N

(b)(4)

Placement or Use

Pouch Label

CR #

(b)(4)

Proof ID: MRC3RD000-E

Rev: (b)(4)



REF MRC3RD000

C3 WAVE ECG CABLE ACCESSORY PACK

1 UNIT

Contents:

- 1 - Drape
- 1 - Remote Cover
- 1 - ECG w/Alligator Clip

LOT

XXXXXXXX



USE BY

1111-11-11



STERILE EO



Rx Only



Medical Components, Inc. 1499 Delp Drive, Harleysville, PA 19438 U.S.A.
Tel: 215-256-4201 Fax: 215-256-1787 www.medcompnet.com

NOT MADE OR MANUFACTURED WITH NATURAL RUBBER LATEX



(01) 0 0884908 13148 2 (17) 111111 (10) XXXXXXXX

Please consult symbols glossary within the IFU

MED LABEL REV. A

FRONT

ØDIM F ±.031

DIM E ±.125

15° ± 2°

SEALED AREA

DIM A ±.125

DIM D ±.062

.375 ±.062 TYP

BACK

DIM B ±.062

SEE DETAIL "A"

SEE NOTE 6

DIM C ±.125

REVISIONS

REV.	DATE	ECR	DESCRIPTION
A	2/1/06	9675	RELEASE TO PRODUCTION
B	10/1/10	14855	REPLACE EXISTING SYMBOLS WITH B INTERNATIONAL SYMBOLS

(b)(4)

VENDOR: (b)(4)

P/N: SEE TABLE

NOTES:

1. MATERIAL: FRONT- 48 ga PET/.002 LDPE
U/C 1073 B TYVEK
BACK-DUPONT 1073 B TYVEK
2. COLOR: FRONT-CLEAR
BACK-WHITE (NOTCHES OPTIONAL)
3. PART TO BE FREE OF DIRT, OIL, GREASE, AND ANY OTHER PARTICULATE CONTAMINATION LARGER THAN .15mm².
4. PART TO BE FREE OF EXCESSIVE SINKS, FLASH BURNS, AND ANY OTHER SURFACE DEFECT.
5. VENDOR CERTIFICATION OF COMPLIANCE REQUIRED.
6. HANG HOLE TO BE CENTERED BETWEEN DIMENSIONS B & E.

DETAIL "A"

SCALE: 4X

DO NOT REUSE

STERILIZED

DO NOT RE-STERILIZE

CAUTION: COMPLEAT ACCOMPANYING DOCUMENTS

KEEP DRY

UPPER LIMIT OF TEMPERATURE

KEEP AWAY FROM RADIATION

DO NOT USE IF PACKAGE IS DAMAGED

UNLESS SPECIFIED, TOLERANCE AS FOLLOWS:

.X = ± .050

.XX = ± .010

.XXX = ± .005

16/ UNLESS SPECIFIED REMOVE ALL BURRS AND SHARP EDGES

ALL INFORMATION IN THIS DRAWING IS THE SOLE PROPERTY OF MED COMP AND IS NOT TO BE DISCLOSED, REPRODUCED OR USED IN ANY WAY WITHOUT THE EXPRESSED PERMISSION OF MED COMP

SCALE:

NTS

INSPECTION KEY

● CRITICAL

○ GENERAL

○ VERIFY

PART#

PART#	DIM A	DIM B	DIM C	DIM D	DIM E	DIM F
3146-1	9.02	6.00	10.158	5.25	.763	.250

medcomp®

1498 DELP DRIVE, MANALAPAN, NJ 08050

(b)(4)

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

Good Morning,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/cdrhcustomerservice?Q=400&D=430&P=433&E=8&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]
Sent: Wednesday, April 11, 2018 4:34 PM
To: Courtney Nix <cnix@medcompnet.com>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,
Patrick McDonald
Phone: X 2302

From: Courtney Nix
Sent: Wednesday, April 11, 2018 4:25 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>
Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me cc'd on everything. Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

I'm offsite this week, I will send this to a regulatory associate right now so they can provide it to you. Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=406&Q=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Deig Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=466&D=436&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=466&D=436&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

Patrick McDonald

From: Patrick McDonald
Sent: Wednesday, April 11, 2018 4:34 PM
To: Courtney Nix; Fitzgerald, Kathleen
Cc: K180567@docs.fda.gov
Subject: RE: K180567
Attachments: 201804111611.pdf

Hi Kathleen,

Please find the attached.

Thanks,
Patrick McDonald
Phone: X 2302

From: Courtney Nix
Sent: Wednesday, April 11, 2018 4:25 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>
Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me cc'd on everything. Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD.

20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD.

20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?Q=400&O=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave.,
Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received.

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&E=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

From: Muslimova, Valentina * [Valentina.Muslimova@fda.hhs.gov]
Sent: 3/9/2018 5:46:34 PM
To: cnix@medcompnet.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K180567/A001 Acknowledgment Notification
Attachments: Acknowledgment Letter.pdf



Acknowledgment Letter

3/9/2018

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

Dear Courtney Nix:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K180567/A001
Received: 3/9/2018
Applicant: Medical Components, Inc. (dba Medcomp)
Device: C3 Wave System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

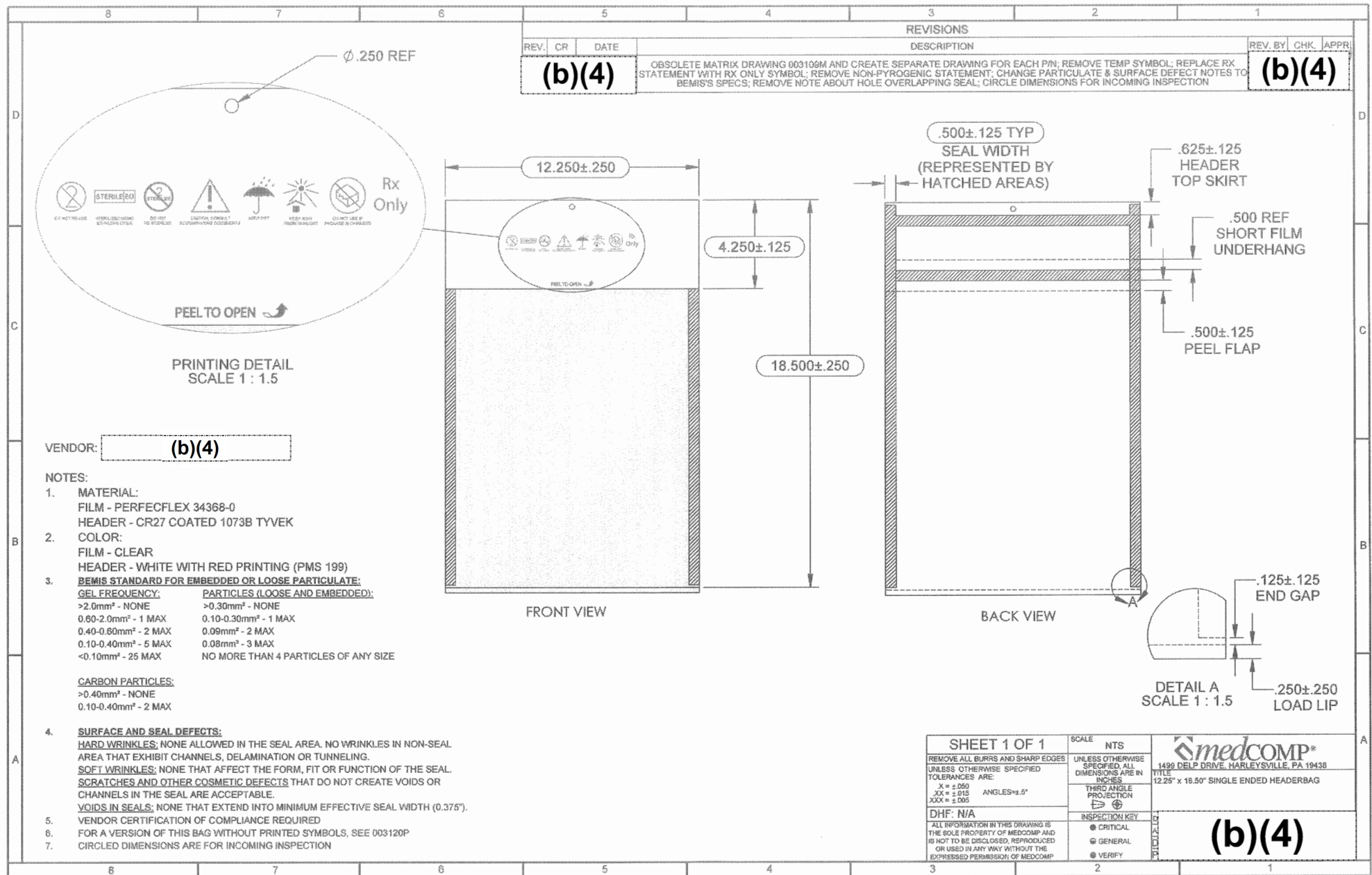
(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft



Hi Kathleen,

Was there suppose to be an attachment?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 12, 2018 8:55 AM

To: Patrick McDonald <pmcdonald@martechmedical.com>; Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>; Patrick McDonald
<pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me ccâ€™d on everything. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdapictures/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>

Hi Kathleen,

Was there suppose to be an attachment?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 12, 2018 8:55 AM

To: Patrick McDonald <pmcdonald@martechmedical.com>; Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: [https://www.research.net/cdrhcustomerservice?Q=400&D=430&P=433&E=\\$S\\$F](https://www.research.net/cdrhcustomerservice?Q=400&D=430&P=433&E=SF)

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [<mailto:pmcdonald@martechmedical.com>]

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me cc'd on everything. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=406&Q=430&B=433&E=8&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Dejo Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=460&D=430&E=433&F=85=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=460&D=430&E=433&F=85=E>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>



Food and Drug Administration
CDRH/ODE/DAGID/GHDB
WO66 RM2510
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6292

Premarket Notification 510(k) Review

Date: April 9, 2018			
Reviewer: Kathleen Fitzgerald			
Subject: Special 510(k)# K180567/S001			
Applicant: Medical Components, Inc. (dba Medcomp)		Device Trade Name: C3 Wave System	
Contact Name: Courtney Nix		Contact Title: Regulatory Affairs Manager, North America and EU	
Correspondent Firm: Medical Components, Inc. (dba Medcomp)		Phone: (215) 256-4201 Ext.2285 Email: cnix@medcompnet.com	
Received Date: March 15, 2018		Due Date: April 14, 2018	
Pro Code(s): LJS Class: II Reg #: 880.5970		Reg Name: Percutaneous, Implanted, Long-Term Intravascular Catheter	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K170934	LJS	C3 Wave System	Medical Components, Inc (Dbas Medcomp)

(b)(5)

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

(b)(5) FDA Reviewer Notes

Digital Signature Concurrence Table (Doc ID: 04500.12.14)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Kathleen E.
Fitzgerald -S

Digitally signed by Kathleen E. Fitzgerald -S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=0010093027
cn=Kathleen E. Fitzgerald -S
Date: 2018.04.09 09:15:14 -04'00'

Hi Kathleen,

(b)(4) Deficiencies

Please keep me ccâ€™d on everything. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix

<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<<http://www.medcompnet.com/>>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphtotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - W066-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>

K180567

510(k) SUMMARY

Special 510K

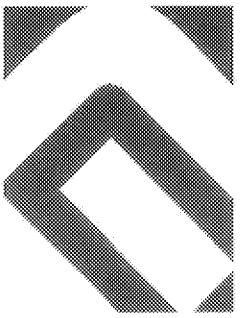
(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

TABLE OF CONTENTS for C3 Wave System Submission

SECTION 1:	Medical Device User Fee Cover Sheet
SECTION 2:	CDRH Premarket Review Submission Cover Sheet
SECTION 3:	Statement of Indications for Use
SECTION 4:	Cover Letter
SECTION 5:	Table of Contents
SECTION 6:	510(k) Site Summary
SECTION 7:	Truthful and Accurate Statement
SECTION 8:	Catalog Codes, Kit Certification, Proposed Labeling
SECTION 9:	(Proposed) MRC3R004 (MRC3RD004) Labeling Proof & Header bag with printed symbols
SECTION 10:	(Predicate) MRC3RD000 Labeling Proof & Header bag with printed symbols
SECTION 11:	Specifications and Device Description
SECTION 12:	(Proposed) (b)(4) Drape Drawing
SECTION 13:	(Predicate) (b)(4) Drape Drawing
SECTION 14:	Sterilization and Shelf Life
SECTION 15:	Sterilization Site Summary
SECTION 16:	EO Residuals for MRC3RD004 (Proposed)
SECTION 17:	Bioburden Exhaustive Recovery for MRC3RD004 (Proposed)
SECTION 18:	Bioburden Routine Results for MRC3RD004 (Proposed)
SECTION 19:	Endotoxin Results for MRC3RD004 (Proposed)
SECTION 20:	(b)(4) 3-Yr AA Shelf Life for MRC3RD004 (Proposed)
SECTION 21:	(b)(4) Transit/Shipping Results for MRC3RD004 (Proposed)
SECTION 22:	Packaging Materials (Memo)
SECTION 23:	(b)(4) Header bag for MRC3RD004 (Proposed)
SECTION 24:	(b)(4) Header bag for MRC3RD000 (Predicate)
SECTION 25:	(Proposed) MRC3RD004-1 Layout
SECTION 26:	(Predicate) MRC3RD000-1 Layout

Medcomp®: C3 Wave System

Section 5: Table of Contents

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

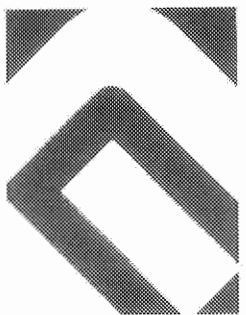
SECTION 27: Substantial Equivalence

SECTION 28: DCAS Table

SECTION 29: Declaration of Standards

SECTION 30: Disclosures

SECTION 31: RTA Checklist



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

Design Control Activities Summary MRC3R004 C3 Wave Accessory Pack

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
------------------------	------	--------------------------	---------------------	-------------------------

(b)(4)

(b)(4) Risk Analysis

March 6, 2018

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

Reference: K180567, C3 Wave System – Incorrect Attachment

To Whom It May Concern,

Medical Components Inc. (dba Medcomp®) submitted a special 510(k) for the C3 Wave System (K180567). After the submission was sent, it was found to have an incorrect attachment. As seen in section 5 *Table of Contents*, the DCAS table was to be included in Section 28. However, the incorrect document was copied over when the submission was burned onto the eCopy. The correct attachment is included (Attachment 002).

We apologize for any inconvenience.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 256-4201 or by email at cnix@medcompnet.com.

Sincerely,

(b)(6)

Courtney

Medcomp® Regulatory Affairs Manager, North America and Europe

Medcomp®: C3 Wave System

Section 27.0

Substantial Equivalence

ATTRIBUTE	Proposed Device: C3 Wave System MRC3RD004	Predicate Device: C3 Wave System MRC3RD000 (K170934)	Comparison Results
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.	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.	Equivalent
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-	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	Equivalent

Medcomp®: C3 Wave System

	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.	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.	
Target Population	Adults	Adults	Equivalent
Components (See below for Full System Components)	ECG Clip Cable, Remote Cover, and Drape	ECG Clip Cable, Remote Cover, and Drape	Equivalent
Drape Dimensions	100"x 86"	45"x40"	Equivalent
Sterilization	EO	EO	Equivalent
Packaging System	12.250"x18.500" Tyvek Headerbag CSR wrapped kit placed inside a Tyvek /LLDPE header bag and shipped within a corrugated shipping carton.	17.500"x10.750" Tyvek Headerbag CSR wrapped kit placed inside a Tyvek /LLDPE header bag and shipped within a corrugated shipping carton.	Equivalent
Testing	ISTA 2A, Endotoxin, EO Residuals, and LAL	ISTA 2A, Endotoxin, EO Residuals, and LAL	Equivalent

Medcomp®: C3 Wave System

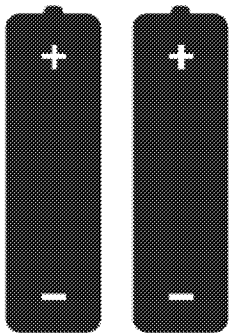
Table of Components, Sterility Status and Reusability for C3 Wave System K170934 vs. K180567

Device Name	Description/Intended Use	Image	Non-Sterile/Sterile	Single/Multi Use	Subject of K170934 Submission	Status
iPad	Screen where the C3 Wave app is displayed.		Non-sterile	Multi Use	Yes	Unchanged
iPad Case	Protective locking iPad case to allow for securement and mounting to IV pole.		Non-sterile	Multi Use	Yes	Unchanged

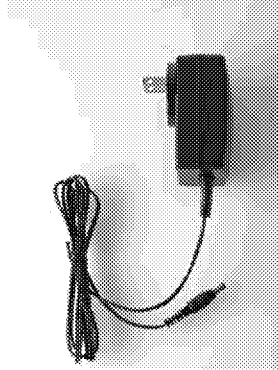
Medcomp®: C3 Wave System

Remote	Remote to navigate through the app.		Non-sterile	Multi Use	Yes	Unchanged
Remote Battery	Coin cell battery to power the remote.		Non-sterile	Multi Use	Yes	Unchanged

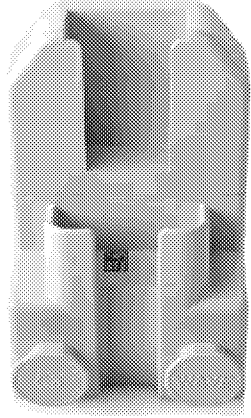
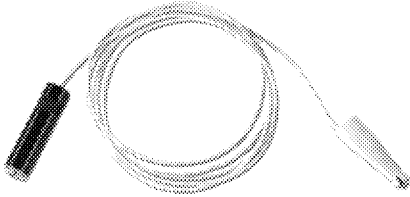
Medcomp®: C3 Wave System

Hub	Connection point for ECG clip and leads. It samples ECG data and transmits it to the iPad.	 A white, heart-shaped medical device with two circular ports on the front and the Medcomp logo.	Non-sterile	Multi Use	Yes	Unchanged
Hub Battery	10460 AAA NiMH rechargeable battery to power hub.	 Two black AAA NiMH rechargeable batteries with white plus and minus signs.	Non-sterile	Multi Use	Yes	Unchanged

Medcomp®: C3 Wave System

Hub Power Supply	Power cord to allow hub to be recharged.		Non-sterile	Multi Use	Yes	Unchanged
Leads	Create the connection between the hub and the electrodes on the patient's chest.		Non-sterile	Multi Use	Yes	Unchanged

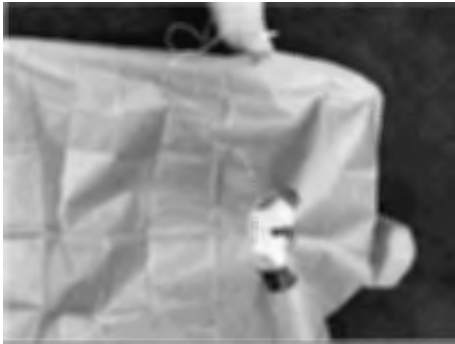
Medcomp®: C3 Wave System

Base	Stand to charge the hub and hold the remote and leads.		Non-sterile	Multi Use	Yes	Unchanged
ECG Clip Cable	Connection between the PICC stylet and hub that transmits the patients ECG waves.		Sterile	Single Use	Yes	Unchanged

Medcomp®: C3 Wave System

Remote Cover	Sterile cover for the remote to allow use in a sterile procedure.	 	Sterile	Single Use	Yes	Unchanged
Electrodes	Sticky pads that go onto the patients chest to create a connection point for the leads.		Non-sterile	Single Use	Yes	Unchanged

Medcomp®: C3 Wave System

Skin Prep	Pads to prep and clean the patient's skin prior to placing the sticky electrodes.		Non-sterile	Single Use	Yes	Unchanged
Window Drape	45" x 40" sterile drape with a puncturable plastic window that can be placed over the hub to allow for the ECG clip to connect to the hub.		Sterile	Single Use	Yes	Unchanged

Medcomp®: C3 Wave System

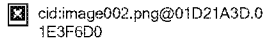
Full Body Drape	100" x 86" full body drape with a puncturable plastic pocket that the hub can be placed in to allow for the ECG clip to connect to the hub. The drape also includes fenestration for the PICC insertion site.		Sterile	Single Use	No	Subject of Submission; Equivalent to Window Drape
------------------------	---	--	---------	------------	----	--

My apologies:

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?Q=400&D=430&B=433&E=8&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Thursday, April 12, 2018 9:23 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>; Patrick McDonald <pmcdonald@martechmedical.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: **(b)(6)** F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

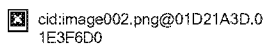
From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 12, 2018 8:55 AM
To: Patrick McDonald <pmcdonald@martechmedical.com>; Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?Q=400&D=430&B=433&E=8&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]
Sent: Wednesday, April 11, 2018 4:34 PM
To: Courtney Nix <cnix@medcompnet.com>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,
Patrick McDonald
Phone: X 2302

From: Courtney Nix
Sent: Wednesday, April 11, 2018 4:25 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>
Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me cc'd on everything. Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.nyu.edu/medcompnet/customer-service?Q=406&D=436&E=433&F=&S=g>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

*Sincerely,
Kathleen Fitzgerald*

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=466&Q=436&B=423&E=8&E=8>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=460&D=430&E=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>



U.S. FOOD & DRUG
ADMINISTRATION

Food and Drug Administration
CDRH/ODE/DAGID/GHDB
WO66 RM2510
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6292

Premarket Notification 510(k) Review

Date: April 9, 2018			
Reviewer: Kathleen Fitzgerald			
Subject: Special 510(k)# K180567/S001			
Applicant: Medical Components, Inc. (dba Medcomp)		Device Trade Name: C3 Wave System	
Contact Name: Courtney Nix		Contact Title: Regulatory Affairs Manager, North America and EU	
Correspondent Firm: Medical Components, Inc. (dba Medcomp)		Phone: (215) 256-4201 Ext.2285 Email: cnix@medcompnet.com	
Received Date: March 15, 2018		Due Date: April 14, 2018	
Pro Code(s): LJS Class: II Reg #: 880.5970		Reg Name: Percutaneous, Implanted, Long-Term Intravascular Catheter	
Predicate Devices:			
Submission #	Pro Code	Device Trade Name	Applicant
K170934	LJS	C3 Wave System	Medical Components, Inc (Db Medcomp)

(b)(5)

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

(b)(5) FDA drafts

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D21A3D.01E3F6D0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com>; Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>; Patrick McDonald
<pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies Please keep me ccâ€™d on everything. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:

www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><<http://www.fda.gov/>>

<image004.jpg><<https://www.facebook.com/FDA>>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image007.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image008.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><<http://www.fda.gov/>>

<image002.jpg><<https://www.facebook.com/FDA>>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image005.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image006.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:

www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald

<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald

<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

Section 14.0

STERILITY INFORMATION

Sterilization Method: The product is sterilized by 100% Ethylene Oxide (EO) Gas¹ in a fixed chamber.

Sterilization Validation: ANSI/AAMI/ISO 11135-1:2014; AAMI TIR 28:2009/(R) 2013

Sterility Assurance Level: SAL is 10⁻⁶.

Sterilization Site:

(1) (b)(4) – ISO 13485 Certified/FDA Registration #

(b)(4) FEI Number # (b)(4)

Validation #: (b)(4)

Address:

(b)(4)

(2) (b)(4) – ISO 13495 Certified/FDA Registration #

(b)(4)

Validation #: (b)(4) dated 02 March 2016

Address:

(b)(4)

(3) (b)(4) – ISO 13485 Certified / FDA Registration #

(b)(4)

Validation #: (b)(4)

Address:

(b)(4)

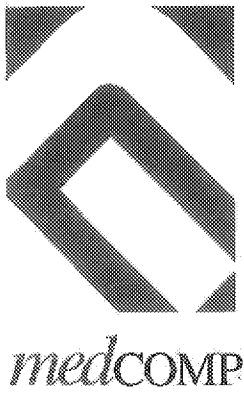
(b)(4)

Description of Validation Method:

(1) The sterilization cycle at (b)(4) 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.

(2) The sterilization cycle at (b)(4) 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.

(3) The sterilization cycle at (b)(4) was developed using the Overkill Approach defined in ANSI/AAMI/ISO 11135-1: 2014, Annex B. The Microbiological Performance Qualification



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

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.

EO Residual Level:

In accordance with AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals, the maximum level is less than to 4 mg/device.

(b)(4)

Pyrogen Test Method:

Tested in accordance with ANSI/AAMI ST72:2011 Bacterial Endotoxin–Test methods, routine monitoring, and alternatives to testing the product is Non-pyrogenic.

(b)(4)

Endotoxin:

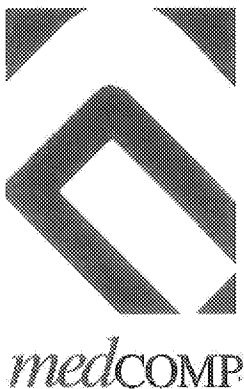
Tested in accordance with ANSI/AAMI ST72:2011 Bacterial Endotoxin–Test methods, routine monitoring, and alternatives to testing the maximum level is 20 EU/device.

(b)(4)

Endotoxin Testing Limit: ≤20 EU/device

Aging/Shelf Life:

(b)(4)



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

(b)(4) Testing

Indications for Use

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 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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

(b)(4)

BIOBURDEN EXHAUSTIVE RECOVERY VALIDATION TEST REPORT
Procedure Reference: (b)(4)

(b)(4) WO#: (b)(4)

Page 1 of 2
Date Received: 10Jul2017

Customer:	Medcomp	Product:	C3 Accessory Pack Drape
	1499 Delp Drive	Cat / Part #:	(b)(4)
	Harleysville, PA 19438	Lot #:	

(b)(4)

(b)(4) Testing

K180567

510(k) SUMMARY

Special 510K

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D21A3D.01E3F6D0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

June 7, 2018</br></br>

<p>FDA acknowledges your amendment to your submission K180567. This submission was closed on 04/12/2018. Therefore, no further action is being taken on this submission and the regulatory status of your submission has not changed. K180567/A002 is now considered closed.</p>

<p>*** This is a system-generated email notification ***</p>

From: Smith, Alysia * [Alysia.Smith@fda.hhs.gov]
Sent: 4/13/2018 4:20:11 PM
To: cnix@medcompnet.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K180567.A002 Acknowledgment Notification
Attachments: K180567.A002 Acknowledgment Notification.pdf

Thank You,

Alysia Smith
Records Management Specialist- 510K Staff
FDA/AMTIS-HeiTech, L.L.C.
Center for Devices and Radiological Health



U.S. FOOD & DRUG
ADMINISTRATION

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

Acknowledgment Letter

4/13/2018

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

Dear Courtney Nix:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K180567/A002
Received: 4/13/2018
Applicant: Medical Components, Inc. (dba Medcomp)
Device: C3 Wave System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

K180567/A001

FDA/CDRH/DCC

MAR 09 2018

RECEIVED

March 6, 2018

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center WO66-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

Reference: K180567, C3 Wave System – Incorrect Attachment

To Whom It May Concern,

Medical Components Inc. (dba Medcomp®) submitted a special 510(k) for the C3 Wave System (K180567) [REDACTED] (b)(4)

(b)(4)

We apologize for any inconvenience.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 256-4201 or by email at cnix@medcompnet.com.

Sincerely,

(b)(6)

Courtney Nix

Medcomp® Regulatory Affairs Manager, North America and Europe

March 6, 2018

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Reference: K180567, C3 Wave System – Incorrect Attachment

To Whom It May Concern,

Medical Components Inc. (dba Medcomp®) submitted a special 510(k) for the C3 Wave System (K180567). (b)(4)

(b)(4)

We apologize for any inconvenience.

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 256-4201 or by email at cnix@medcompnet.com.

Sincerely,

(b)(6)

Courtney Nix

Medcomp® Regulatory Affairs Manager, North America and Europe

Section 8

Proposed Labeling

Table 8.1 Catalog Code and Description

Catalog Code	Description
MRC3RD004	C3 Wave ECG Cable Accessory Pack

Table 8.2 Kit Certification: MRC3RD004

KIT COMPONENT	MATERIAL FORMULATION	STATUS
(1) ECG Clip Cable P/N: (b)(4)	Reviewed in K170934	Reviewed in K170934
(1) C3 Remote Cover P/N: (b)(4)	Reviewed in K170934	Reviewed in K170934 (b)(4)
(1) Full Body Drape P/N: (b)(4)	(b)(4)	Subject of Submission
(1) C3 Wave IFU (Replacement) Domestic P/N: (b)(4)	Information for Users	Reviewed in K170934

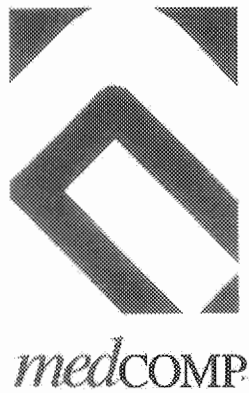
We certify that the kit components listed above are either (1) legally marketed pre-amendment devices, (2) exempt from Premarket Notification, or (3) have been found substantially equivalent through the Premarket Notification process for the use(s) for which the kit is to be intended. We are not claiming a new use for these components.

These components are purchased non-sterile, assembled into a kit, labeled and sterilized by Ethylene Oxide.

Table 8.3: Proposed Labeling

Part Number	Description
MRC3RD004*	C3 Wave ECG Cable Accessory Pack
MRC3RD000	C3 Wave ECG Cable Accessory Pack

* Label included is for MRC3R000, the content remains the same for the MCRC3RD004



1499 Delp Drive
Harleysville, PA 19438
Tel: 215-256-4201
Fax: 215-256-1787
www.medcompnet.com

Technical drawing of a medical device, showing two views: a top view (left) and a side view (right).

Top View (Left):

- Dimensions: 16.5, 12, 10, 5, 12, 14, 11, 12.
- Callouts: SMMS: 1x1.5 (3pcs), UNFOLD, UNFOLD, UNFOLD, UNFOLD, UNFOLD, UNFOLD.
- Material callouts: Top: SMMS 3x24.5 (2pcs); 3x18 (1pc); Base: Tape; Top: Release paper 7.5x9 (2pcs); Base: Tape 1x6(4pcs); 1x7 (4pcs).
- Label: PATIENT SIDE.

Side View (Right):

- Dimensions: 15, 16.5, 11x10, 23±1, 4, 44±1, 100±2, 86±2.
- Callouts: CUT 17, CUT 23, UNFOLD, UNFOLD.

Bill of Materials Table:

ITEM	DESCRIPTION	MATERIAL	QTY.	PART NO.
4	CLEAR WINDOW (0.015mm)	LDPE	N/A	
3	CLEAR WINDOW (0.05mm)	LDPE	N/A	
2	BLUE ABSORBENT RE-INFORCEMENT		N/A	
1	BLUE CLOTH SMMS	POLYPROPYLENE	N/A	

REVISIONS Table:

REV.	DATE	CR	DESCRIPTION
1	5/16/16	19590	RELEASE TO PROTOTYPE

Notes:

1. MATERIAL: SEE B.O.M.
2. COLOR: SEE B.O.M.
3. PART TO BE FREE OF DIRT, OIL, GREASE, AND ANY OTHER PARTICULATE CONTAMINATION LARGER THAN .15mm².
4. VENDOR CERTIFICATE OF COMPLIANCE REQUIRED.

Vendor Information:

VENDOR: (b)(4)
VENDOR: (b)(4)

MedComp Information:

MEDCOMP
1499 DELP DRIVE, HARLEYSVILLE, PA 19438

Scale: NTS

Inspection Key:

- CRITICAL
- GENERAL
- VERIFY

Other Text:

UNLESS OTHERWISE SPECIFIED TOLERANCES ARE:
X = ±.050
XX = ±.010
XXX = ±.005
REMOVE ALL BURRS AND SHARP EDGES
ALL INFORMATION IN THIS DRAWING IS THE SOLE PROPERTY OF MEDCOMP AND IS NOT TO BE DISCLOSED, REPRODUCED OR USED IN ANY WAY WITHOUT THE EXPRESSED PERMISSION OF MEDCOMP

March 12, 2018</br></br>

Acceptance Review Notification - Refuse To Accept (RTA)

<p>We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold. </p>

<p>Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:</p>

<p style="padding-left:50">U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - W066-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002</p>

<p>FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.</p>

<p>Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission. </p>

<p>Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.</p>

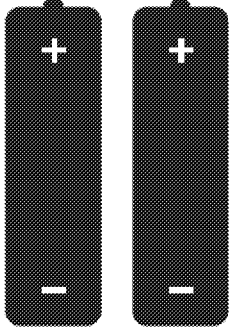
<p>For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf.</p>

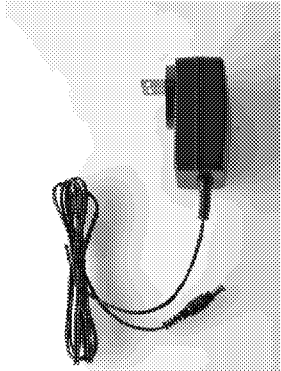
<p>*** This is a system-generated email notification ***</p>

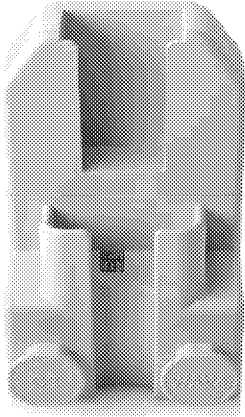
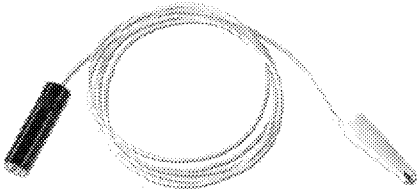
Table of Components, Sterility Status and Reusability for C3 Wave System K170934 vs. K180567

Device Name	Description/Intended Use	Image	Non-Sterile/Sterile	Single/Multi Use	Subject of K170934 Submission	Status
iPad	Screen where the C3 Wave app is displayed.		Non-sterile	Multi Use	Yes	Unchanged
iPad Case	Protective locking iPad case to allow for securement and mounting to IV pole.		Non-sterile	Multi Use	Yes	Unchanged

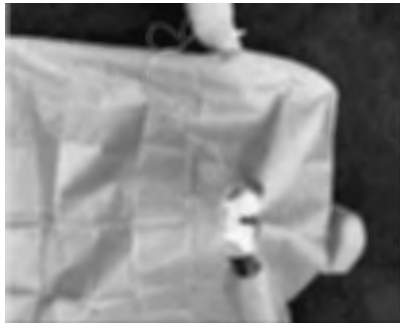
Remote	Remote to navigate through the app.		Non-sterile	Multi Use	Yes	Unchanged
Remote Battery	Coin cell battery to power the remote.		Non-sterile	Multi Use	Yes	Unchanged

Hub	Connection point for ECG clip and leads. It samples ECG data and transmits it to the iPad.		Non-sterile	Multi Use	Yes	Unchanged
Hub Battery	10460 AAA NiMH rechargeable battery to power hub.		Non-sterile	Multi Use	Yes	Unchanged

Hub Power Supply	Power cord to allow hub to be recharged.		Non-sterile	Multi Use	Yes	Unchanged
Leads	Create the connection between the hub and the electrodes on the patient's chest.		Non-sterile	Multi Use	Yes	Unchanged

Base	Stand to charge the hub and hold the remote and leads.		Non-sterile	Multi Use	Yes	Unchanged
ECG Clip Cable	Connection between the PICC stylet and hub that transmits the patients ECG waves.		Sterile	Single Use	Yes	Unchanged

Remote Cover	Sterile cover for the remote to allow use in a sterile procedure.		Sterile	Single Use	Yes	Unchanged
Electrodes	Sticky pads that go onto the patients chest to create a connection point for the leads.		Non-sterile	Single Use	Yes	Unchanged

Skin Prep	Pads to prep and clean the patient's skin prior to placing the sticky electrodes.		Non-sterile	Single Use	Yes	Unchanged
Window Drape	45" x 40" sterile drape with a puncturable plastic window that can be placed over the hub to allow for the ECG clip to connect to the hub.		Sterile	Single Use	Yes	Unchanged

Full Body Drape	100" x 86" full body drape with a puncturable plastic pocket that the hub can be placed in to allow for the ECG clip to connect to the hub. The drape also includes fenestration for the PICC insertion site.		Sterile	Single Use	No	Subject of Submission; Equivalent to Window Drape
------------------------	---	--	---------	------------	----	--

Design Control Activities Summary MRC3R004 C3 Wave Accessory Pack

Device Modification	Risk	Verification Activity	Acceptance Criteria	Results of Verification
(b)(4)				

(b)(4) Risk Analysis

Appendix C

Contains Nonbinding Recommendations

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K

Date Received by DCC:

Lead Reviewer:

Branch:

Division:

Center/Office:

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Special 510(k) Criteria			
The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below. Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.			
		Yes	No
1.	510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	☒	☐
Comments:			
2.	Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	☒	☐
Comments:			
3.	Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	☒	☐
Comments:			
4.	The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.	☒	☐
Comments:		(b)(4) Deficiencies	

Does the submission meet all 4 criteria above?

- ☒ Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

Contains Nonbinding Recommendations**Organizational Elements**

Failure to include these items should not result in an RTA designation.

***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**

		Yes	No	*Page #
1.	Submission contains a Table of Contents.	☒	☐	
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	☒	☐	
3.	All pages of the submission are numbered. <i>All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2...).</i>	☒	☐	
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) <i>If type of 510(k) is not designated, review as a Traditional 510(k).</i>	☒	☐	
Comments: (b)(4) Deficiencies				

Elements of a Complete Submission (RTA Items)**(21 CFR 807.87 unless otherwise indicated)**

Submission should be designated RTA if not addressed

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.

***Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**

		Yes	No	N/A	*Page #
A.	Administrative				
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).	☒	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Comments:				
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):				
	a.	Device trade/proprietary name	☒	☐	
	b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	☒	☐	
	Comments:				
3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance " <u>Alternative to Certain Prescription Devices Labeling Requirements.</u> ") <i>See recommended format</i> <i>(http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).</i>		☒	☐	
	Comments:				
4.	Submission contains a 510(k) Summary or 510(k) Statement. <i>Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.</i>		☒	☐	
	Comments:				
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). <i>See recommended format</i> <i>(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).</i>		☒	☐	
	Comments:				
6.	Submission is a Class III 510(k) Device. <i>Select "N/A" only if submission is not a Class III 510(k).</i>		☐		☒
	a.	Contains Class III Summary and Certification <i>See recommended content</i>	☐	☐	☒

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).					
Comments: (b)(4) Deficiencies					
7.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device. <i>Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514). This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).</i>	☒	☒		(b)(4) Deficiencies
a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. <i>To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.</i> <i>Select "N/A" if the submitter states there were no prior submissions.</i>	☐	☐	☒	
Comments:					
Combination Product Provisions – Per 503(g) of the FD&C Act. Select N/A if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison.				☒	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
8.	Submission identifies the product as a combination product.	☐	☒		
9.	The combination product contains as a constituent part an approved drug as defined in 21 USC 503(g)(5)(B). Select "N/A" if the combination product does not contain as a constituent part an approved drug. Please also select "N/A" if a right of reference or use for the drug constituent part(s) is included with the submission. If "N/A" is selected, part a below is omitted from the checklist.	☐		☒	
a.	The submission includes appropriate patent statement or certification and a statement that the applicant will give notice, as applicable. 21 USC 503(g)(5)(A)&(C).	☐	☒		
Comments:					
B.	Device Description				
10.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. <i>If "N/A" is selected, parts a and b below are omitted from the checklist.</i>	☐		☒	
a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. <i>Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.</i>	☐	☐	☒	
b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and	☐	☐	☒	

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.		Yes	No	N/A	*Page #
	provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. <i>Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.</i>				
	Comments:				
11.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		
	Comments:				
12.	The submission includes descriptive information for the device, including the following:				
a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐		
b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐		
c.	A list and description of each device for which clearance is requested. <i>Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.</i>	☒	☐	☐	
d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). <i>In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design,</i>	☒	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.						
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.			Yes	No	N/A	*Page #
		size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.				
		Comments:				
	13.	A description of all device modification(s) including rationale for each modification.	☒	☐		
		Comments:				
	14.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. <i>Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.</i>	☒		☐	
	a.	Submission includes a list of all components and accessories to be marketed with the subject device.	☒	☐		
	b.	Submission includes a description (as detailed in item 12a., 12b., and 12d. above) of each component or accessory. <i>Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.</i>	☒	☐	☐	
	c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	☒	☐		
		Comments:				
C.	Substantial Equivalence Discussion					
	15.	Submitter has identified a predicate device(s), including the following information:				
	a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is</i>	☒	☐		

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.							
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
			available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).				
		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	☒	☐		
		Comments:					
	16.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>					
		a.	Indications for use <i>If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.</i>	☒	☐		
		b.	Technology, including features, materials, and principles of operation <i>Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.</i> <i>FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.</i>	☒	☐		
D.	Design Control Activities						

Contains Nonbinding Recommendations

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
17.	Design Control Activities Summary includes all of the following:				
a.	Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components AND the results of the analysis	☒	☐		
b.	Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria	☒	☐		
c.	Declaration of conformity with design controls. All 3 below must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in 21 CFR 820.30. iii. Statement is signed by the individual responsible for these activities.	☒	☐		
Comments:					
E.	Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)				
18.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		
a.	All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	☒	☐		
Comments:					
19.	Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	☒	☐		
Comments:					

Contains Nonbinding Recommendations

Decision: Accept _____ Refuse to Accept _____

If Accept, notify the applicant

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

*Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K180567

Date Received by DCC: Mar 5, 2018

Lead Reviewer: Kathleen Fitzgerald

Branch: GHDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below.
Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.	X	
Comments:		

Does the submission meet all 4 criteria above?

- ☒ Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance " Alternative to Certain Prescription Devices Labeling Requirements. ") <i>See recommended format.</i> (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) <i>See recommended format.</i> (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)	X				
6) Submission is a Class III 510(k) device.			X		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		

8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			×		
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		×			
10) The submission includes descriptive information for the device, including the following:				×	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.		×			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		×			
c) A list and description of each device for which clearance is requested.	×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. <u>OR</u> Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
Comments: (b)(4) Deficiencies					
11) A description of all device modification(s) including rationale for each modification.	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X			X	
a) Submission includes a list of all components and accessories to be marketed with the subject device.		X			
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.		X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance <u>AND</u> A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.		X			
Comments: (b)(4) Deficiencies					
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)</i>	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>				X	
a) Indications for Use	X				
b) Technology, including 3D printing, FDA QDR, HMD, and other digital technologies	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
Comments:	(b)(4) Deficiencies					
D. Design Control Activities						
15) Design Control Activities Summary includes all of the following:					×	
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.			×			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.			×			
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in <u>21 CFR 820.30</u> . iii. Statement is signed by the individual responsible for these activities.		×				
Comments:	(b)(4) Deficiencies					
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)						
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).			×			
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.			×			
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).			×		×	
Comments:	(b)(4) Deficiencies					

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Kathleen E. Fitzgerald -S Digitally signed by Kathleen E. Fitzgerald -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010093027, cn=Kathleen E. Fitzgerald -S Date: 2018.03.06 16:17:09 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	

* Branch and Division review of checklist and concurrence with with decision required.
Branch and Division digital signature optional.

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/cdrhcustomerservice?C=460&D=430&R=433&E=88=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?Q=460&D=430&R=433&E=88>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?C=400&D=436&B=433&E=85&F=>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Deip Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

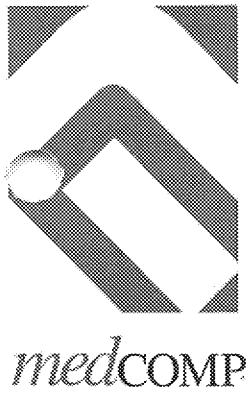
FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

FDA/CDRH/DCC

APR 13 2018

RECEIVED

April 12, 2018

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center WO66-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

K180567/A002

Reference: K180567, C3 Wave System – April 12th, 2018 Interactive Review

To Whom It May Concern,

Medical Components Inc. (dba Medcomp®) submitted a special 510(k) for the C3 Wave System (K180567). Lead reviewer, Kathleen Fitzgerald, sent interactive review questions on April 11, 2018 requesting that the responses be sent back by 10AM on Thursday April 12th, 2018. Below are Ms. Fitzgerald's questions with the corresponding Medcomp responses.

(b)(4) Deficiencies

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 256-4201 or by email at cnix@medcompnet.com.

Sincerely,

(b)(6)

Patrick McDonald on behalf Courtney Nix

Regulatory Affairs Manager, North America and Europe

Medical Components Inc.

1499 Delp Drive

Harleysville PA, 19438 USA

22

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><<http://www.fda.gov/>>

<image004.jpg><<https://www.facebook.com/FDA>>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image007.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image008.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an

advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><<http://www.fda.gov/>>

<image002.jpg><<https://www.facebook.com/FDA>>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image005.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image006.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA request 2022-117, released by DPH on 05-31-2024

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>

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

(b)(4)

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?Q=400&D=430&B=433&E=88&F>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?Q=400&D=430&B=433&E=88&F>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Deip Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***



Medcomp Label Proof

Proof ID

MRC3R004-E

Rev

(b)(4)



Catalog Number

MRC3R004

CR #

(b)(4)

Revision History:

(b)(4)



Medcomp Label Proof

Catalog Code

MRC3R004

Label Stock P/N

(b)(4)

Placement or Use

Shipping Box Label

CR #

(b)(4)

Proof ID: MRC3R004-E

Rev: (b)(4)



REF MRC3R004

C3 WAVE ECG CABLE
ACCESSORY PACK

8 UNITS

LOT

XXXXXXXX



USE BY

1111-11-11

STERILE EO



Rx Only

CE
XXXX

EC REP

MPS Medical Product Service GmbH
Borngasse 20
35619 Braunfels, Germany



Medical Components, Inc. 1499 Delp Drive, Harleysville, PA 19438 U.S.A.
Tel: 215-256-4201 Fax: 215-256-1787 www.medcompnet.com

NOT MADE OR MANUFACTURED WITH NATURAL RUBBER LATEX



(01) 5 0884908 12706 4 (17) 111111 (10) XXXXXXXX

MED LABEL REV. A

Version



Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Page 2 of 4



Medcomp Label Proof

Catalog Code

MRC3R004

Label Stock P/N

(b)(4)

Placement or Use

Customer Survey Label

CR #

(b)(4)

Proof ID: MRC3R004-E

Rev:

(b)(4)

We want your feedback!
Please visit:



<https://www.medcompnet.com/contact/Feedback/>

Version

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

5

Page 3 of 4



Medcomp Label Proof

Catalog Code

MRC3R004

Label Stock P/N

(b)(4)

Placement or Use

Pouch Label

CR #

(b)(4)

Proof ID: MRC3R004-E

Rev: (b)(4)



REF MRC3R004

C3 WAVE ECG CABLE ACCESSORY PACK

Contents:
1 - Full Body Drape
1 - Remote Cover
1 - ECG w/Alligator Clip

Περιεχόμενα:
1 - σκεύασμα ολόσωμο
1 - Κάλυμμα τηλεχειριστηρίου
1 - Καλώδιο ECG με συνδεδεμένο κροκοδείνιο

Contenido:
1 - paño quirúrgico de cuerpo entero
1 - Capa de comando remoto
1 - ECG con pinzas cocodrilo

Inhalt:
1 - Ganzkörperbedeckung
1 - Hülle für die Fernbedienung
1 - EKG mit Krokodilklemme

Contenido:
1 - vinjeta de cuerpo entero
1 - Funda para el control remoto
1 - ECG con pinzas cocodrilo

Isi tartalom:
1 - Idem vécset öltető
1 - Uzenetket karnandó öltető
1 - EKG ve Krokodil Pecs

Contenu:
1 - champ corps entier
1 - Housses de la télécommande
1 - ECG avec pince crocodile

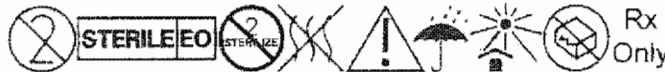
Innehåll:
1 - operationsklän, helkropp
1 - Fjärrkontrollfäse
1 - EKG med krokodilklemma

Obsah:
1 - Celotělový návlak
1 - Vzdálený kryt
1 - EKG s krokodílkami

Inhoud:
1 - Afdekdoek
1 - Zak voor afstandsbediening
1 - ECG met alligatorklem

Contenuto:
1 - Telo corpo intero
1 - Copertura del telecomando
1 - ECG con lermo a coccodrillo

Tartalom:
1 - teljes testet fedő (zokkölendő)
1 - Távirányító-borítás
1 - EKG-kábel krokodilfogszal



1 UNIT



MPS Medical Product Service GmbH
Bismarckstrasse 20
35619 Braunfels, Germany



Medical Components, Inc. 1499 Delo Drive, Harleysville, PA 19438 U.S.A.
Tel: 215-256-4201 Fax: 215-256-1787 www.medcompnet.com

NOT MADE OR MANUFACTURED WITH NATURAL RUBBER LATEX

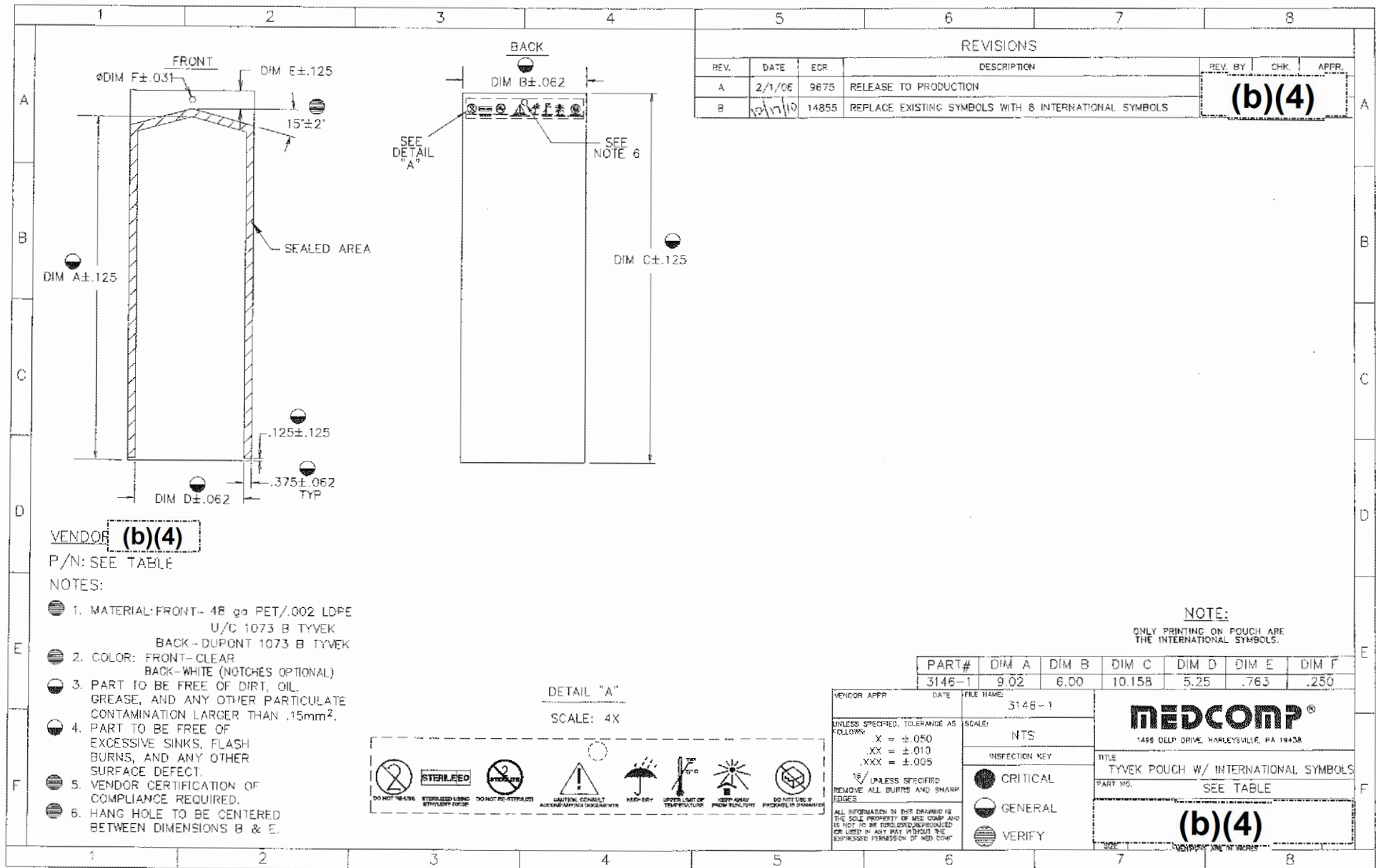
LOT XXXXXXXX

USE BY 1111-11-11



(01) 0 0884908 12708 9 (17) 111111 (10) XXXXXXXX

MED LABEL REV. A



(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

My apologies, please see the attached document with revisions.

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D21A3D.01E3F6D0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdapotos/>>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Thursday, April 12, 2018 9:23 AM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>; Patrick McDonald <pmcdonald@martechmedical.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Was there suppose to be an attachment?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 12, 2018 8:55 AM

To: Patrick McDonald
<pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>; Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>; Patrick McDonald
<pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Please keep me ccâ€™d on everything. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

Iâ€™m offsite this week, I will send this to a regulatory associate right now so they can provide it to you. Thanks!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Records processed under FOIA Request 2022-0701; Released by CDRH on 05-31-2025

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><<http://www.fda.gov/>>

<image002.jpg><<https://www.facebook.com/FDA>>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image005.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image006.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:

www.medcompnet.com<<http://www.medcompnet.com>>

From: Kathleen Fitzgerald

<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald

<kathleen.fitzgerald@fda.hhs.govmailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>

Section 4:

Submission Cover Letter

Medcomp intends to market the following device into commercial distribution:

Submission Type:	Special 510(k)
Submission Date:	February 28, 2018
Submitter:	Medical Components Inc. (dba. Medcomp®) 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: (215) 256-9191
Registration Number:	2518902
Contact Person:	Courtney Nix Regulatory Affairs Manager, North America and Europe
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

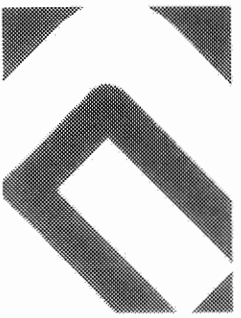
Device Equivalence: This device is substantially equivalent to the following device:

K170934 – C3 Wave System (Code MRC3RD000)

This device does not present additional risk to patients or different considerations regarding safety and effectiveness than those presented by the predicate devices.

4-1

Medcomp®: C3 Wave System
Section 4: Cover letter



medCOMP

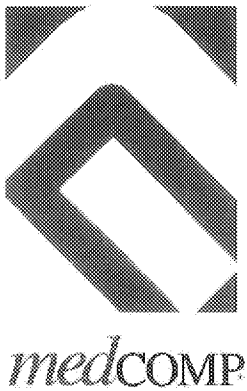
1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

Basis for 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: MRC3RD000, MRC3RD001, and MRC3RD003 (NOTE: a "D" was added to the catalog codes to distinguish international codes from domestic post clearance. In the submission on file, the catalog codes were listed as MRC3R000, MRC3R001, and MRC3R003. This change to the catalog codes was documented as support and filed with the submission as an addendum).

(b)(4)

(b)(4)

Per FDA guidance *eCopy Program for Medical Device Submissions*, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thanks you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 859-0995 or by email at cnix@medcompnet.com.

Sincerely,

(b)(6)

Courtney Nix
Medical Components Inc. (dba. Medcomp®)
Regulatory Affairs Manager, North America and Europe
Cnix@medcompnet.com

Medcomp®: C3 Wave System
Section 4: Cover letter

4-2

SHEET 1 OF 1

APPROVED

By Kim Deibler at 2:43 pm, 2/2/18

VER DIBUJO 05662 PARA INSTRUCCIONES DE PLEGADO
SEE DRAWING 05662 FOR FOLDING INSTRUCTIONS

PLACE 3146-1 SEALED POUCH ON TOP
OF DRAPE, WRAP BOTH IN 3011 WRAP

SELLAR BOLSA HEADERBAG
SEAL HEADERBAG

30381/PPO9041

4732-2

40567US

30780-103

VER VISTA A DETALLE "A"
SEE DETAIL VIEW "A"

3011

4148-3
COLOCAR ETIQUETA DE ENCUESTA AL CLIENTE EN
ESTA UBICACION APROX.
PLACE CUSTOMER SURVEY LABEL AT APPROXIMATE
LOCATION

3212P

3937
PPO9014

3146-1/PPO9036

30780-1

SELLAR POUCH
SEAL POUCH

30780-102

12 UNIDADES POR
CAJA DE ENVIO
12 UNITS PER
SHIPPING CARTON

4732-1

VISTA A DETALLE "A"
DETAIL VIEW "A"

COLOR Y FORMA DE LOS COMPONENTES PUEDE VARIAR. LOS COMPONENTES
MOSTRADOS EN FOTOS SON SOLO PARA ESPECIFICAR COLOCACION.
(COLOR AND SHAPE OF COMPONENTS MAY VARY. COMPONENTS SHOWN IN PHOTOS ARE TO
SPECIFY PLACEMENT ONLY)

A	21150	12/14/2017	CREATE AND IMPLEMENT MRC3RD000-1 LAYOUT DRAWING	DLB	(b)(4)
REV.	DATE	CR #	DESCRIPTION	REV. BY	

REVISIONS

DWG APPLIES TO:
MRC3RD000

medcomp
1499 DELP DRIVE, HARLEYSVILLE, PA 19438
TITLE: C3 WAVE ECG CABLE ACCESSORY PACK

DWG/PART NO.: MRC3RD000-1

B [DRAWN BY]
SIZE [APPROVED] (b)(4)

UNLESS OTHERWISE SPECIFIED, ALL DIMENSIONS ARE IN INCHES
ALL INFORMATION IN THIS DRAWING IS THE SOLE PROPERTY OF MEDCOMP AND IS NOT TO BE DISCLOSED, REPRODUCED OR USED IN ANY WAY WITHOUT THE EXPRESSED PERMISSION OF MEDCOMP

From: Muslimova, Valentina * [Valentina.Muslimova@fda.hhs.gov]
Sent: 3/15/2018 5:20:11 PM
To: cnix@medcompnet.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K180567/S001 Acknowledgment Notification
Attachments: Acknowledgment Letter.pdf



U.S. FOOD & DRUG
ADMINISTRATION

Acknowledgment Letter

3/15/2018

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

Dear Courtney Nix:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K180567/S001
Received: 3/15/2018
Applicant: Medical Components, Inc. (dba Medcomp)
Device: C3 Wave System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?C=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Deip Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=406&U=430&B=433&E=65#E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=406&U=430&B=433&E=65#E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Deip Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

Section 27.0

Substantial Equivalence

(b)(4) Draft

(b)(4) Draft

Section 11

Specifications & Device Description

11.1 Device Drawings:

Table 11.1: C3 Wave System Device Drawings

Part Number	Device
(b)(4)	Proposed Drape
	Predicate Drape

11.2 Design Philosophy:

The C3 Wave Replacement of X-Ray is designed to provide a continuous display of electrocardiograph [ECG] waveforms to guide placement of peripherally-inserted central catheters [PICC] in the lower third of the Superior Vena Cava [SVC] of a patient.

The system uses three ECG leads placed on the patient's chest and a fourth lead connected to the conductive stylet in a PICC. These ECG waveforms are wirelessly transmitted to a tablet which allows the operator to view and record changes to this waveform as the tip of the catheter approaches the heart. As the PICC catheter approaches the right 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. By close examination of the P-Wave changes a user is able to safely place a PICC without the need to confirm with x-ray.

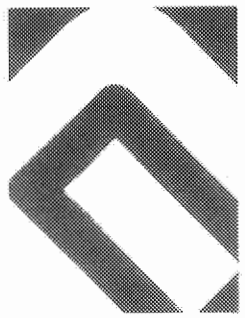
The C3 Wave system must only be operated by a skilled nurse, physician, or trained medical professional who has been qualified in placement of PICC's and trained in the proper use of this device.

The C3 Wave System includes:

- an iPad® monitor running the mobile application software
- the C3 hub which includes rechargeable batteries and a power supply
- a remote control with non-rechargeable batteries
- ECG snap leads.

Procedural accessories include:

- ECG electrodes and prep pads
- sterile remote cover
- sterile patient drape
- sterile PICC Clip Connector



medCOMP

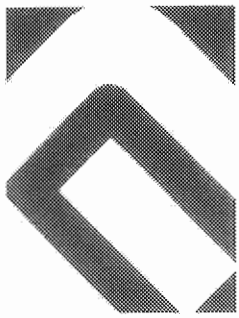
1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com



medCOMP

1499 Delp Drive

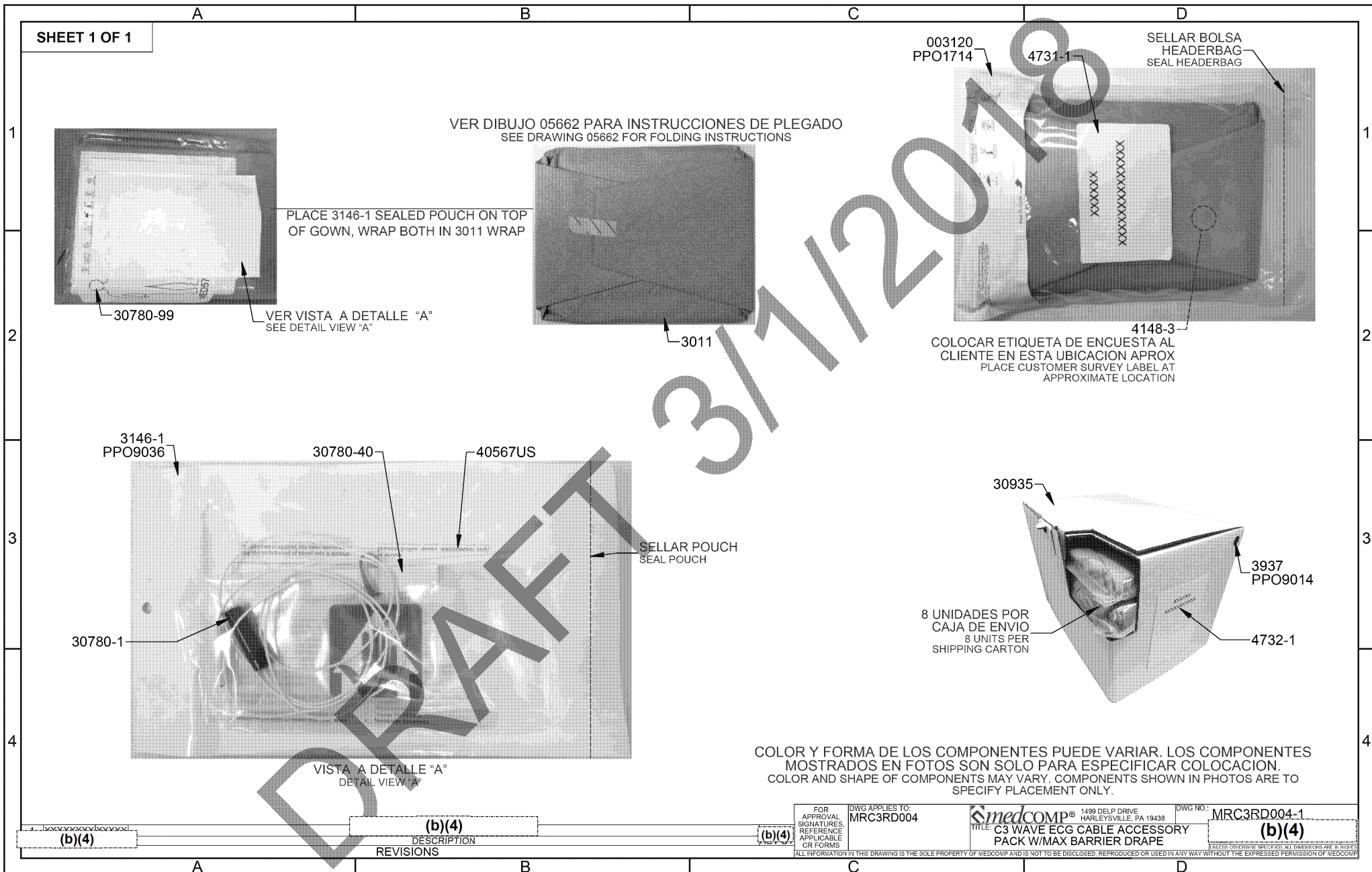
Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

The C3 Wave System can communicate with web-based EMR systems and air-print compatible printers over an 802.11 compatible WiFi connection. The hub and remote both use Bluetooth technology to communicate wirelessly with the C3 Wave iPad app.





U.S. FOOD & DRUG
ADMINISTRATION

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 -
S

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

(b)(4)



(b)(4)

(b)(4)

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=468&D=436&E=433&E=83&E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Deip Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: K180567@docs.fda.gov
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.nps/cdrmcustomerservice?Q=466&D=436&B=433&E=45&F=>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/cdrhcustomerservice?Q=400&Q=430&S=433&E=85&E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024
Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:

www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>
Sent: Thursday, April 05, 2018 9:43 AM
To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>
Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>
Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><<http://www.fda.gov/>>

<image004.jpg><<https://www.facebook.com/FDA>>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><<http://www.youtube.com/user/USFoodandDrugAdmin>>

<image007.jpg><<http://www.flickr.com/photos/fdaphotos/>>

<image008.jpg><<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination,

copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphtphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

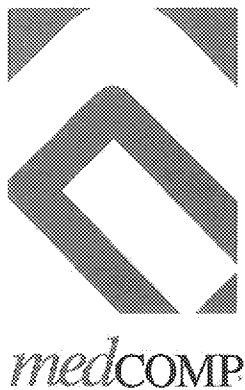
Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

April 5, 2018

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center WO66-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Reference: K180567, C3 Wave System – April 5th, 2018 Interactive Review

To Whom It May Concern,

(b)(4) Deficiencies

(b)(4) Deficiencies

Thanks Kathleen! Would you like us to put it on letterhead?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 12, 2018 9:56 AM

To: Courtney Nix <cnix@medcompnet.com>; Patrick McDonald <pmcdonald@martechmedical.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

My apologies, please see the attached document with revisions.

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

 cid:image002.png@01D21A3D.01E3F6D0

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/s/cdrhcustomerservice?g=440&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Thursday, April 12, 2018 9:23 AM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>; Patrick McDonald <pmcdonald@martechmedical.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Was there suppose to be an attachment?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 12, 2018 8:55 AM

To: Patrick McDonald <pmcdonald@martechmedical.com>; Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

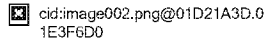
CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov



Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received: <https://www.research.net/cdrhcustomerservice?O=480&D=436&E=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,
Patrick McDonald
Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=406&D=436&R=433&E=&S=g>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Deip Dr. • Harleysville, PA 19333

T: 215-256-4201 x 2285 C: **(b)(6)** F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=466&D=436&B=433&E=85=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 7:12 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Hi Courtney,

(b)(4) Deficiencies

*Sincerely,
Kathleen Fitzgerald*

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=466&D=436&B=433&E=85=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

Hi Kathleen,

Please find the attached.

Thanks,
Patrick McDonald
Phone: X 2302

From: Courtney Nix
Sent: Wednesday, April 11, 2018 4:25 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Cc: K180567@docs.fda.gov; Patrick McDonald <pmcdonald@martechmedical.com>
Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 4:21 PM, Courtney Nix <cnix@medcompnet.com> wrote:

Hi Kathleen,

I'm offsite this week, I will send this to a regulatory associate right now so they can provide it to you. Thanks!

Thanks, Courtney Nix
Regulatory Affairs Manager,
North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

*Sincerely,
Kathleen Fitzgerald*

Nurse Consultant/Lead Reviewer
CDRH/ODE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?Q=469&Q=436&B=433&E=8&S=6>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Friday, April 06, 2018 10:25 AM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Deip Dr. • Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov

<image003.png>

<image004.jpg> <image005.jpg> <image006.jpg> <image007.jpg> <image008.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.news/cdrh/customerservice?Q=468&D=436&E=433&E=85=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

Hi Courtney,

(b)(4) Deficiencies

Sincerely,
Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer
CDRH/OCE/DAGRID/GHDB
U.S. Food & Drug Administration
White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292
kathleen.fitzgerald@fda.hhs.gov
<image001.png>

<image002.jpg> <image003.jpg> <image004.jpg> <image005.jpg> <image006.jpg>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/cdrhcustomerservice?Q=460&D=430&B=433&E=2&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [<mailto:cnix@medcompnet.com>]
Sent: Tuesday, March 13, 2018 3:59 PM
To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>
Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,
Courtney Nix
Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.
1499 Delp Dr. • Harleysville, PA 19438
T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191
Email: CNix@medcompnet.com Web: www.medcompnet.com

From: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com>
Cc: Kathleen Fitzgerald <kathleen.fitzgerald@fda.hhs.gov>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024
addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s please refer to the guidance document available at
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k)Summary.FINAL.doc>

MEMO

TO: DHF 18001

FROM: (b)(6)
Medcomp Principal Electrical Engineer

(b)(6)

DATE: 2/27/2018

SUBJECT: MRC3R004/MRC3RD004* Materials of Packaging Components

The packaging components in the C3 Wave System accessory pack MRC3R004/MRC3RD004* are as follows:

	Packaging Component		
	Bottom Web	Top Web	Adhesive
Material	(b)(4)		
CAS Number			
Applicable Packaging			
Catalog Code	MRC3R004	MRC3R004	MRC3R004

The pouch and headerbag are sealed by applying a heated bar under pressure for a select amount of time to bond the bottom web (Tyvek film layer) to the top web (clear LDPE film layer coated with polyester).

* NOTE: MRC3R004 and MRC3RD004 are identical, the "D" was added in the catalog code that will be distributed in the US.



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

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).

Form Approved: OMB No. 0910-0011 Expiration Date: August 31, 2019. See instructions to OMB Stamp.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html		
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) MEDCOMP 1499 DELP DR HARLEYSVILLE PA 19438 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****5560		2. CONTACT NAME Courtney Nix 2.1 E-MAIL ADDRESS Cnix@medcompnet.com 2.2 TELEPHONE NUMBER (include Area code) 215-2564201 2.3 FACSIMILE (FAX) NUMBER (Include Area code)
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) Select an application type:		
☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request		3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application Supplement Types: ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:		
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)		
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.		
☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only		☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). ☐ YES ☒ NO		
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.		

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

01-Mar-2018

FD-360 (08-96)

["Close Window"](#) [Print Cover sheet](#)

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0] <http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0] <https://www.facebook.com/FDA>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

Thanks Kathleen! Would you like us to put it on letterhead?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Sent: Thursday, April 12, 2018 9:56 AM

To: Courtney Nix <cnix@medcompnet.com>; Patrick McDonald <pmcdonald@martechmedical.com>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image006.jpg@01D21A3D.01E3F6D0] <http://www.flickr.com/photos/fdaphotos/>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]
Sent: Thursday, April 12, 2018 9:23 AM
To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>; Patrick McDonald <pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>
Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>
Subject: RE: K180567

Hi Kathleen,

Was there suppose to be an attachment?

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 12, 2018 8:55 AM

To: Patrick McDonald
<pmcdonald@martechmedical.com<mailto:pmcdonald@martechmedical.com>>; Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0]<https://www.facebook.com/FDA>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>
[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdaphotos/>>
[cid:image007.jpg@01D21A3D.01E3F6D0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:
<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Patrick McDonald [mailto:pmcdonald@martechmedical.com]

Sent: Wednesday, April 11, 2018 4:34 PM

To: Courtney Nix <cnix@medcompnet.com<<mailto:cnix@medcompnet.com>>>; Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov<<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>>

Cc: K180567@docs.fda.gov<<mailto:K180567@docs.fda.gov>>

Subject: RE: K180567

Hi Kathleen,

Please find the attached.

Thanks,

Patrick McDonald

Phone: X 2302

From: Courtney Nix

Sent: Wednesday, April 11, 2018 4:25 PM

To: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>>

Cc: K180567@docs.fda.gov<<mailto:K180567@docs.fda.gov>>; Patrick McDonald
<pmcdonald@martechmedical.com<<mailto:pmcdonald@martechmedical.com>>>

Subject: Re: K180567

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

On Apr 11, 2018, at 4:21 PM, Courtney Nix
<cnix@medcompnet.com<mailto:cnix@medcompnet.com>> wrote:

Hi Kathleen,

(b)(4) Deficiencies

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Apr 11, 2018, at 2:50 PM, Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Please email me the requested information by 4-9-2018 by 11AM EST. Thank you.

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image003.png><http://www.fda.gov/>

<image004.jpg><https://www.facebook.com/FDA>

<image005.jpg><https://twitter.com/US_FDA>

<image006.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image007.jpg><http://www.flickr.com/photos/fdaphotos/>

<image008.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Records processed under FOIA Request # 22-1717, Released by CDRH on 05-04-2024

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Sent: Monday, March 12, 2018 7:56 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>

Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration

Center for Devices and Radiological Health

Document Control Center - WO66-G609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

<K180567.510(k) Summary.FINAL.doc>

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: December 31, 2013 See PRA Statement on page 5.	
Date of Submission 03/02/2018		User Fee Payment ID Number (b)(4)	
		FDA Submission Document Number (if known) N/A	
SECTION A TYPE OF SUBMISSION			
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☐ Traditional ☒ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information ☐ Third Party
		Request for Feedback ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (specify):	
IDE ☐ Original Submission ☐ Amendment ☐ Supplement	Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information	Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information
		Other Submission ☐ 513(g) ☐ Other (describe submission):	
Have you used or cited Standards in your submission? ☒ Yes ☐ No (If Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Medical Components, Inc. (dba Medcomp)		Establishment Registration Number (if known) 2518902	
Division Name (if applicable) N/A		Phone Number (including area code) (215) 256-4201 (ext 2285)	
Street Address 1499 Delp Drive		FAX Number (including area code) (215) 256-9191	
City Harleysville	State / Province PA	ZIP/Postal Code 19438	Country USA
Contact Name Courtney Nix			
Contact Title Regulatory Affairs Manager, North America and EU		Contact E-mail Address Cnix@medcompnci.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (specify below)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager ☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment ☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address
☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (specify below)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (specify below)	
☐ Response to FDA correspondence:		
☐ Other Reason (specify):		
<i>N/A</i> <i>DM 01 MAR 2018</i>		
SECTION D2 REASON FOR APPLICATION - IDE		
☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
☐ New Device	☐ Additional or Expanded Indications	☐ Change in Technology
☒ Other Reason (specify): Creating a new code with a new, larger drape. This catalog code was removed from the prior submission due to lack of testing.		

SECTION E**ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS**

Product codes of devices to which substantial equivalence is claimed

1	LIS
5	

(b)(4)

Summary of, or statement concerning, safety and effectiveness information

- ☒ 510 (k) summary attached
☐ 510 (k) statement

Information on devices to which substantial equivalence is claimed (if known)

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
1 K170934	1 C3 Wave System	1 Medical Components, Inc (dba Medcomp)
2	2	2
3	3	3
4	4	4
5	5	5
6	6	6

N/A
PSM 01 MAR 2018

SECTION F**PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS**

Common or usual name or classification name

Catheter, intravascular, Therapeutic Long-Term Greater Than 30 Days

Trade or Proprietary or Model Name for This Device	Model Number
1 C3 Wave System	1 MRC3RD004
2	2
3	3
4	4
5	5

N/A
PSM 01 MAR 2018

FDA document numbers of all prior related submissions (regardless of outcome)

1	2	3	4	5	6
7	8	9	10	11	12

N/A
PSM 01 MAR 2018

Date Included in Submission

☒ Laboratory Testing☐ Animal Trials☐ Human Trials**SECTION G****PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS**

Product Code

LIS

C.F.R. Section (if applicable)

880.579

Device Class

☐ Class I☒ Class II☐ Class III☐ Unclassified

Classification Panel

General Hospital

Indications (from labeling)

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.

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.

FDA Document Number (if known)

SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number		☒ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name Medical Components, Inc. (dba Medcomp)		Establishment Registration Number 2518902			
Division Name (if applicable) N/A		Phone Number (including area code) (215) 256-4201			
Street Address 1499 Delp Drive		FAX Number (including area code) (215) 256-9191			
City Harleysville		State / Province PA	ZIP Code 19438	Country USA	
Contact Name Courtney Nix		Contact Title Regulatory Affairs Manager, North America and Europe		Contact E-mail Address Cnix@medcompnet.com	

☒ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number (b)(4)		☐ Manufacturer ☒ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)			
Division Name (if applicable) (b)(4)		Phone Number (including area code) (b)(4)			
Street Address (b)(4)		FAX Number (including area code) (b)(4)			
City (b)(4)		State / Province (b)(4)	ZIP Code (b)(4)	Country (b)(4)	
Contact Name (b)(4)		Contact Title (b)(4)		Contact E-mail Address	

☒ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number (b)(4)		☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)			
Division Name (if applicable) (b)(4)		Phone Number (including area code) (b)(4)			
Street Address (b)(4)		FAX Number (including area code) (b)(4)			
City (b)(4)		State / Province (b)(4)	ZIP Code (b)(4)	Country (b)(4)	
Contact Name (b)(4)		Contact Title		Contact E-mail Address (b)(4)	

Note: Submission of this information does not affect the need to submit a 2891 or 2891a Device Establishment Registration form.

FDA Document Number (if known)

SECTION H (Continued)

☒ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number			
(b)(4)		(b)(4)			
Division Name (if applicable)		Phone Number (including area code)			
(b)(4)		(b)(4)			
Street Address		FAX Number (including area code)			
(b)(4)		(b)(4)			
City		State / Province	ZIP Code	Country	
(b)(4)		(b)(4)	(b)(4)	(b)(4)	
Contact Name		Contact Title		Contact E-mail Address	
(b)(4)		(b)(4)		(b)(4)	

☒ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer	☒ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number			
(b)(4)		(b)(4)			
Division Name (if applicable)		Phone Number (including area code)			
(b)(4)		(b)(4)			
Street Address		FAX Number (including area code)			
(b)(4)					
City		State / Province	ZIP Code	Country	
(b)(4)		(b)(4)	(b)(4)	(b)(4)	
Contact Name		Contact Title		Contact E-mail Address	
(b)(4)		(b)(4)		(b)(4)	

☐ Original ☐ Add ☐ Delete		Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Manufacturer	☐ Contract Sterilizer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number			
Division Name (if applicable)		Phone Number (including area code)			
		N/A PSM 01 MAR 2018			
Street Address		FAX Number (including area code)			
City		State / Province	ZIP Code	Country	
Contact Name		Contact Title		Contact E-mail Address	

SECTION I UTILIZATION OF STANDARDS					
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. 10993-7	Standards Organization ISO	Standards Title 14-408: ISO 10993-7 Second edition 2008-10-15, biological evaluation of medical devices - part 7: ethylene oxide sterilization residuals [including: technical corrigendum 1 (2009)]. (Sterility)	Version Second Edition	Date 10/15/2008
2	Standards No. 11135	Standards Organization ISO	Standards Title 14-452: ISO 11135 Second edition 2014, sterilization of health-care products - ethylene oxide - requirements for the development, validation and routine control of a sterilization process for medical devices. (Sterility)	Version Second Edition	Date 01/01/2014
3	Standards No. ANSI ST72	Standards Organization AAMI / ANSI	Standards Title 14-360: AAMI / ANSI ST72:2011/(R)2016, bacterial endotoxins - test methods, routine monitoring, and alternatives to batch testing. (Sterility)	Version 2011/(R)2016	Date 2011/(R)2016
4	Standards No. 11607-1	Standards Organization ISO	Standards Title ISO 11607-1: 2009+A1:2014, packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)]. (Sterility)	Version 2009+A1:2014	Date 2009+A1:2014
5	Standards No. 11607-2	Standards Organization ISO	Standards Title 14-455: ISO 11607-2 First edition 2006-04-15, packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)]. (Sterility)	Version First Edition	Date 04/15/2006
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date

Please include any additional standards to be cited on a separate page.

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

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

The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

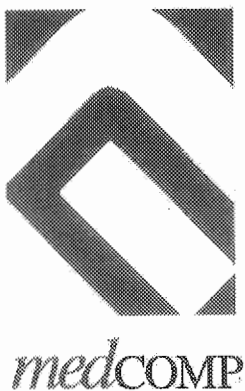
Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 2: CDRH Coversheet and Kit Certification

Table 2.1 Catalog Code and Description

Catalog Code	Description
MRC3RD004	C3 Wave ECG Cable Accessory Pack



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com



U.S. FOOD & DRUG
ADMINISTRATION

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 -
S

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

Form Approved: OMB No. 0910-0120

Expiration Date: January 31, 2017

See PRA Statement below.

Indications for Use

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

Medcomp®: C3 Wave System
K170934

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

Medcomp®: C3 Wave System
K170934

	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).

April 12, 2018</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Kathleen Fitzgerald.</p>

<p>*** This is a system-generated email notification ***</p>

Good Afternoon Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002
(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<<http://www.fda.gov/>>

[cid:image003.jpg@01D21A3D.01E3F6D0]<<https://www.facebook.com/FDA>>

[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>

[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image007.jpg@01D21A3D.01E3F6D0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Friday, April 06, 2018 10:25 AM

To: Fitzgerald, Kathleen <Kathleen.Fitzgerald@fda.hhs.gov>

Cc: K180567@docs.fda.gov

Subject: RE: K180567

Hi Kathleen,

Please see attached. Let me know if you have any additional questions.

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU
Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web:
www.medcompnet.com<http://www.medcompnet.com/>

From: Fitzgerald, Kathleen
<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Sent: Thursday, April 05, 2018 9:43 AM

To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>

Cc: K180567@docs.fda.gov<mailto:K180567@docs.fda.gov>

Subject: RE: K180567

Good Morning Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

[cid:image002.png@01D21A3D.01E3F6D0]<http://www.fda.gov/>

[cid:image003.jpg@01D21A3D.01E3F6D0] <<https://www.facebook.com/FDA>>
[cid:image004.jpg@01D21A3D.01E3F6D0] <https://twitter.com/US_FDA>
[cid:image005.jpg@01D21A3D.01E3F6D0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>
[cid:image006.jpg@01D21A3D.01E3F6D0] <<http://www.flickr.com/photos/fdaphotos/>>
[cid:image007.jpg@01D21A3D.01E3F6D0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 7:12 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: Re: K180567 is on Hold Pending Your Response

Thanks Kathleen, sorry for the confusion! Have a great night!

Thanks, Courtney Nix

Regulatory Affairs Manager,

North America and Europe

On Mar 13, 2018, at 7:08 PM, Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>> wrote:

Hi Courtney,

(b)(4) Deficiencies

Sincerely,

Kathleen Fitzgerald

Nurse Consultant/Lead Reviewer

CDRH/ODE/DAGRID/GHDB

U.S. Food & Drug Administration

White Oak, Bldg. 66, Rm. 2510, 10903 New Hampshire Ave., Silver Spring, MD. 20993-0002

(301) 796 - 6292

kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>

<image001.png><http://www.fda.gov/>

<image002.jpg><https://www.facebook.com/FDA>

<image003.jpg><https://twitter.com/US_FDA>

<image004.jpg><http://www.youtube.com/user/USFoodandDrugAdmin>

<image005.jpg><http://www.flickr.com/photos/fdaphotos/>

<image006.jpg><http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

Excellent customer service is important to us. Please take a moment to provide feedback regarding the customer service you have received:

<https://www.research.net/s/cdrhcustomerservice?O=400&D=430&B=433&E=&S=E>

THIS MESSAGE IS INTENDED FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone found above.

This communication is consistent with 21 CFR 10.85(k) and constitutes an informal communication that represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the view expressed.

From: Courtney Nix [mailto:cnix@medcompnet.com]

Sent: Tuesday, March 13, 2018 3:59 PM

To: Fitzgerald, Kathleen

<Kathleen.Fitzgerald@fda.hhs.gov<mailto:Kathleen.Fitzgerald@fda.hhs.gov>>

Subject: RE: K180567 is on Hold Pending Your Response

Hi Kathleen,

(b)(4) Deficiencies

Thanks,

Courtney Nix

Courtney Nix | Regulatory Affairs Manager, North America and EU

Medical Components, Inc.

1499 Delp Dr. â- Harleysville, PA 19438

T: 215-256-4201 x 2285 C: (b)(6) F: 215-256-9191

Email: CNix@medcompnet.com<mailto:CNix@medcompnet.com> Web: www.medcompnet.com<http://www.medcompnet.com/>

From: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>
Sent: Monday, March 12, 2018 7:56 AM
To: Courtney Nix <cnix@medcompnet.com<mailto:cnix@medcompnet.com>>
Cc: Kathleen Fitzgerald
<kathleen.fitzgerald@fda.hhs.gov<mailto:kathleen.fitzgerald@fda.hhs.gov>>
Subject: K180567 is on Hold Pending Your Response

March 12, 2018

Acceptance Review Notification - Refuse To Accept (RTA)

We have completed the administrative acceptance review of your premarket notification (510(k)) submission K180567. Our review indicates that your 510(k) submission does not meet the criteria established for administrative completeness. Thus, we regret to inform you that we are unable to conduct a substantive review of your submission at this time and are placing it on RTA hold.

Please submit two copies of your response (1 eCopy and 1 paper copy), referencing the 510(k) number K180567, addressing the elements identified as missing or inconsistent in the attached checklist to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA will permit your 510(k) submission to remain on hold for a maximum of 180 days from the date of this email. If you do not correct the missing or inconsistent elements identified in the checklist by September 8, 2018, we will consider this 510(k) submission to be withdrawn, and we will delete it from our review system.

Upon receipt of the requested information, FDA will conduct another administrative review of your 510(k) submission.

Should you have questions about this email, you may contact Kathleen Fitzgerald, the lead reviewer assigned to your 510(k) submission.

For additional information regarding the Refuse to Accept Policy for 510(k)s<<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>> please refer to the guidance document available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM315014.pdf>.

*** This is a system-generated email notification ***

Section 7

Truthful and Accurate Statement

PREMARKET NOTIFICATION
TRUTHFUL AND ACCURATE STATEMENT
(As required by 21 CFR 807.87)

I certify, in my capacity as President of Medical Components Inc. (dba Medcomp®),
that to the best of my knowledge, all data and information submitted in this
premarket notification for the C3 Wave System, is truthful and accurate and that no
material fact has been omitted.

(b)(6)

Timothy M. Schweikert

28 FEB 2018

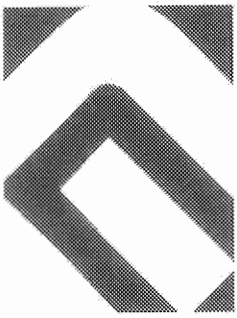
Date

N/A - Unknown

Premarket Notification Number

7-1

Medcomp®: C3 Wave System
Section 7: 510(k) Truthful and Accurate Statement



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com



March 12, 2018

Food and Drug Administration

Center for Devices and Radiological Health

Document Mail Center WO66-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Reference: K180567, C3 Wave System – March 12th, 2018 RTA

(b)(4) Deficiencies

(b)(4) Deficiencies

From: Muslimova, Valentina * [Valentina.Muslimova@fda.hhs.gov]
Sent: 3/5/2018 6:14:17 PM
To: cnix@medcompnet.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K180567 Acknowledgment Notification
Attachments: Acknowledgment Letter.pdf



U.S. FOOD & DRUG
ADMINISTRATION

Acknowledgment Letter

3/5/2018

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

Dear Courtney Nix:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K180567
Received: 3/5/2018
Applicant: Medical Components, Inc. (dba Medcomp)
Device: C3 Wave System

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K180567

Date Received by DCC: Mar 5, 2018

Lead Reviewer: Kathleen Fitzgerald

Branch: GHDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below.
Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.	X	
Comments:		

Does the submission meet all 4 criteria above?

- ☒ Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2022-47117; Released by CDRH on 05-31-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	×				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	×				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	×				
4) Submission contains a 510(k) Summary or 510(k) Statement.	×				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)	×				
6) Submission is a Class III 510(k) device.			×		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.	×				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			×		
B. Device Description					
8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			×		
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		×			
10) The submission includes descriptive information for the device, including the following:				×	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.		×			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.		×			
c) A list and description of each device for which clearance is requested.	×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X				
Comments:	(b)(4) Deficiencies				
11) A description of all device modification(s) including rationale for each modification.	X				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X			X	
a) Submission includes a list of all components and accessories to be marketed with the subject device.		X			
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.		X			
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.		X			
Comments:	(b)(4) Deficiencies				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)</i>	X				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	X				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>				X	
a) Indications for Use	X				
b) Technology, including 3D printing, FDA QIR, HMD, and other digital technologies	X				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
Comments:	(b)(4) Deficiencies					
D. Design Control Activities						
15) Design Control Activities Summary includes all of the following:					×	
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.			×			
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.			×			
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in <u>21 CFR 820.30</u> . iii. Statement is signed by the individual responsible for these activities.		×				
Comments:	(b)(4) Deficiencies					
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)						
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).			×			
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.			×			
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).			×		×	
Comments:	(b)(4) Deficiencies					

Decision:

☐ Accept

☒ Refuse to Accept

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off

Kathleen E.
Fitzgerald -S

Digitally signed by Kathleen E. Fitzgerald -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA,
ou=People, 0.9.2342.19200300.100.1.1=0010093027,
cn=Kathleen E. Fitzgerald -S
Date: 2018.03.06 16:17:09 -05'00'

Branch Chief Sign-Off
(digital signature
optional)*

Alan M.
Stevens -S

Digitally signed by Alan M. Stevens -S
DN: c=US, o=U.S. Government,
ou=HHS, ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=13001892
11, cn=Alan M. Stevens -S
Date: 2018.03.12 07:55:17 -04'00'

Division Sign-Off
(digital signature
optional)*

* Branch and Division review of checklist and concurrence with with decision required.
Branch and Division digital signature optional.

April 12, 2018

Food and Drug Administration

Center for Devices and Radiological Health

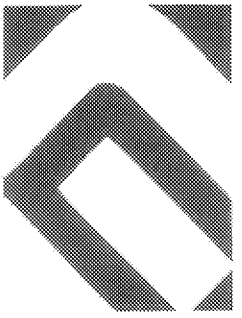
Document Mail Center WO66-0609

10903 New Hampshire Avenue

Silver Spring, MD 20993-0002

Reference: K180567, C3 Wave System – April 12th, 2018 Interactive Review

To Whom It May Concern



medCOMP

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

(b)(4) Deficiencies

Thank you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 256-4201 or by email at cnix@medcompnet.com.

Sincerely,

Patrick McDonald on behalf Courtney Nix

Regulatory Affairs Manager, North America and Europe

Medical Components Inc.

1499 Delp Drive

Harleysville PA, 19438 USA



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Special 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K180567

Date Received by DCC: Mar 15, 2018

Lead Reviewer: Kathleen Fitzgerald

Branch: GHDB

Division: DAGRID

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during the substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Special 510(k) Criteria

The submission should not be reviewed as a Special 510(k) if "No" is selected for any of the 4 criteria below.
Complete the Refuse to Accept Checklist for a Traditional 510(k) if submission is converted.

	Yes	No
1) 510(k) is submitted to modify a legally marketed device (predicate) AND the Special 510(k) submission is submitted by the holder of the 510(k) for the predicate device.	X	
Comments:		
2. Indications for Use of the proposed device are unchanged from the legally marketed device (predicate).	X	
Comments:		
3) Fundamental scientific technology of the proposed device is unchanged from the legally marketed device (predicate).	X	
Comments:		
4) The submission includes only summary-level information (i.e., NO test reports with performance data). Note that if performance data are provided and are conducted under design validation (21 CFR 820.30(g)), for example, to demonstrate continued conformance with a special control or recognized standard, then a Special 510(k) may be appropriate.	X	
Comments:		

Does the submission meet all 4 criteria above?

- ☒ Yes, submission meets criteria for a Special 510(k). Continue checklist below.
- ☐ No, submission does not meet criteria for a Special 510(k). Discontinue this RTA checklist, convert to a Traditional and apply the Traditional checklist.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X		

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2022-47117; Released by CDRH on 05-31-2024					
	Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	X				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	X				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format. (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	X				
4) Submission contains a 510(k) Summary or 510(k) Statement.	X				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm)	X				
6) Submission is a Class III 510(k) device.			X		
7) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.	X				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.			X		
B. Device Description					
8) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.	X				
a) The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X				
b) The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118			X		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2022-47117; Released by CDRH on 05-31-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
9) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	×				
10) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	×				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×				
c) A list and description of each device for which clearance is requested.	×				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	×				
11) A description of all device modification(s) including rationale for each modification.	×				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	×				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	×				
b) Submission includes a description (as detailed in item 10(a), 10(b) and 10(d) above) of each component or accessory.	×				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	×				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online.</i> <i>(http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)</i>	×				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] <i>See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.</i>					
a) Indications for Use	×				
b) Technology, including features, materials, and principles of operation	×				
D. Design Control Activities					
15) Design Control Activities Summary includes all of the following:					
a) Identification of Risk Analysis methods(s) used to assess the impact of the modification on the device and its components AND the results of the analysis.	×				
b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria.	×				
c) Declaration of conformity with design controls. All 3 must be present to answer "Yes." i. Statement that all verification and validation activities were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. ii. Statement that manufacturing facility is in conformance with design control procedure requirements as specified in <u>21 CFR 820.30</u> . iii. Statement is signed by the individual responsible for these activities.	×				
E. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
16) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	×				
a) All changes in proposed labeling resulting from device modification(s) are highlighted or prominently identified.	×				
17) Statement that the intended use of the modified device, as described in the labeling, has not changed as a result of the modification(s).	×				

Decision:

☒ Accept

☐ Refuse to Accept

Records processed under FOIA Request 2022-4717; Released by CDRH on 05-31-2024

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table

Reviewer Sign-Off

Kathleen E.
Fitzgerald -S

Digitally signed by Kathleen E. Fitzgerald -
S
DN: c=US, o=U.S. Government, ou=HHS,
ou=FDA, ou=People,
0.9.2342.19200300.100.1.1=0010093027,
cn=Kathleen E. Fitzgerald -S
Date: 2018.03.16 10:43:41 -04'00'

Branch Chief Sign-Off
(digital signature
optional)*

Division Sign-Off
(digital signature
optional)*

* Branch and Division review of checklist and concurrence with with decision required.
Branch and Division digital signature optional.

Medcomp®: C3 Wave System

MAR 05 2018

RECEIVED

Section 4:

Submission Cover Letter

Medcomp intends to market the following device into commercial distribution:

Submission Type:

Special 510(k)

K180567

Submission Date:

February 28, 2018

Submitter:

Medical Components Inc.
(dba. Medcomp®)
1499 Delp Drive
Harleysville, PA 19438
Tel: (215) 256-4201
Fax: (215) 256-9191

Registration Number:

2518902

Contact Person:

Courtney Nix
Regulatory Affairs Manager, North
America and Europe

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

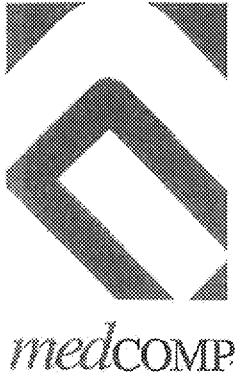
Device Equivalence: This device is substantially equivalent to the following device:

K170934 – C3 Wave System (Code MRC3RD000)

This device does not present additional risk to patients or different considerations regarding safety and effectiveness than those presented by the predicate devices.

4-1

Medcomp®: C3 Wave System
Section 4: Cover letter



1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Fax: 215-256-1787

www.medcompnet.com

Medcomp®: C3 Wave System

Basis for 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: MRC3RD000, MRC3RD001, and MRC3RD003 (NOTE: a "D" was added to the catalog codes to distinguish international codes from domestic post clearance. In the submission on file, the catalog codes were listed as MRC3R000, MRC3R001, and MRC3R003. This change to the catalog codes was documented as support and filed with the submission as an addendum). (b)(4)

(b)(4)

Per FDA guidance *eCopy Program for Medical Device Submissions*, an electronic copy is being provided with this submission and it is an exact duplicate of the original paper submission.

We consider our intent to market this device as confidential commercial information and request that it be treated as such by the FDA. We have taken precautions to protect the confidentiality of the intent to market these devices. We understand that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331(q).

Thanks you in advance for your consideration of our application. If there are any questions, please feel free to contact me by phone at (215) 859-0995 or by email at cnix@medcompnet.com.

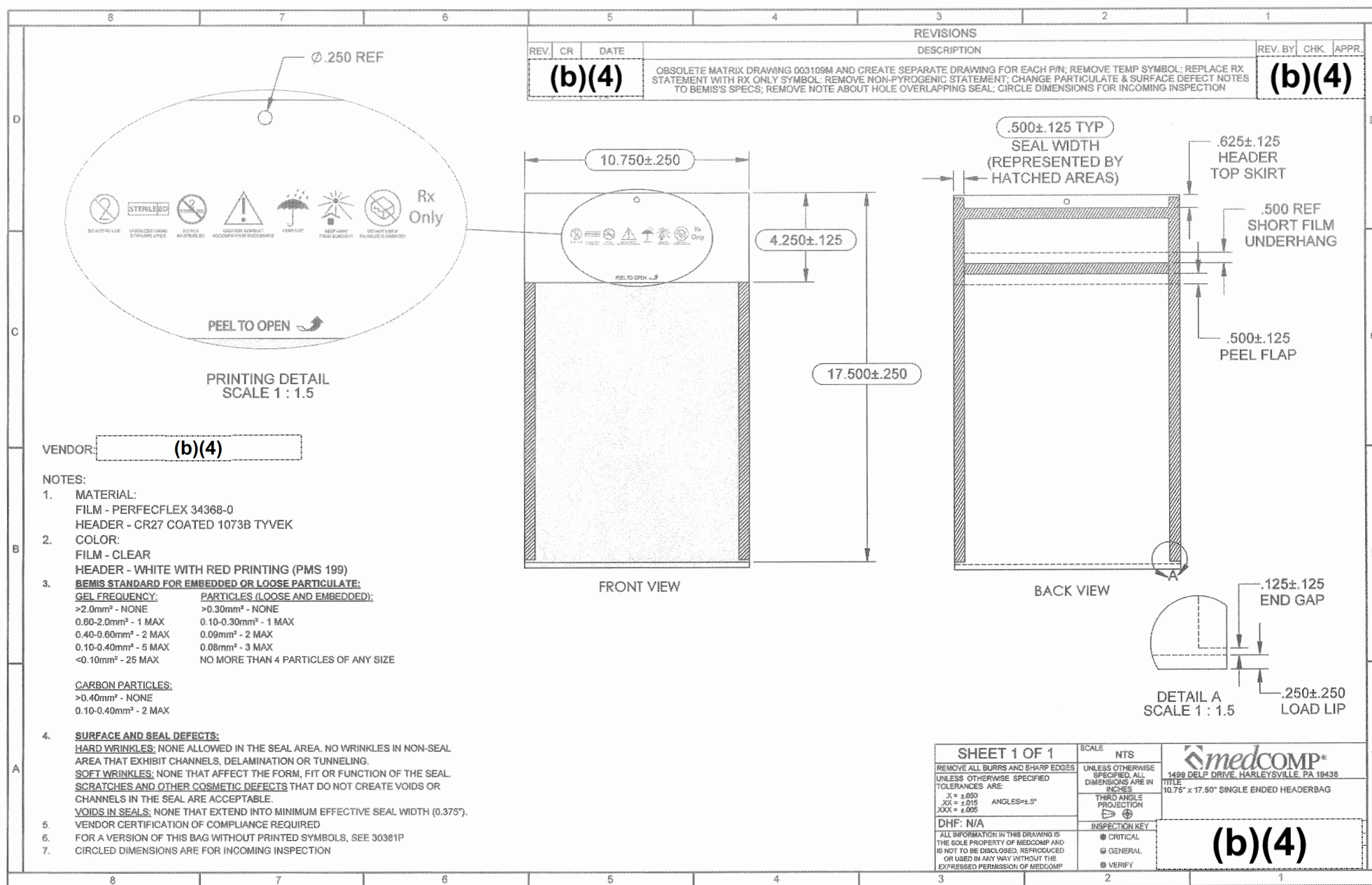
Sincerely,

(b)(6)

Courtney Nix
Medical Components Inc. (dba. Medcomp®)
Regulatory Affairs Manager, North America and Europe
Cnix@medcompnet.com

Medcomp®: C3 Wave System
Section 4: Cover letter

4-2



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).

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120

Expiration Date: 06/30/2020

See PRA Statement below.

Indications for Use

510(k) Number (if known)

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

(b)(4)

RESIDUAL TESTING REPORT

Procedure Reference: **(b)(4)**

Customer:
Medcomp
1499 Delp Drive
Harleysville, PA 19438

Laboratory Reference No.:
(b)(4)

Page 1 of 1

(b)(4)

(b)(4) Testing

(b)(4) Testing



PRODUCT VERIFICATION/VALIDATION RESULTS
SUMMARY

ORIGINATOR: (b)(4) DATE: 02/23/2018

PROJECT NUMBER: (b)(4) STUDY/TEST: VERIFICATION ☐
VALIDATION ☒ V NUMBER: (b)(4)

DEVICE DESCRIPTION: C3 ECG Cable Accessory Pack (MRC3R004) - ISTA 2A Shipping Test

(b)(4)

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing



PRODUCT VERIFICATION/VALIDATION TEST
PROTOCOL

ORIGINATOR: (b)(4) DATE: 01/09/2018

PROJECT NUMBER: (b)(4) STUDY/TEST: VERIFICATION ☐
VALIDATION ☒ V NUMBER: (b)(4)

DEVICE DESCRIPTION: C3 ECG Cable Accessory Pack (MRC3R004) ISTA 2A Shipping Test

(b)(4)

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Protocol

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

(b)(4) Testing

Biocompatibility testing	Pass cytotoxicity, sensitization and irritation per ISO 10993.	Cytotoxicity testing was conducted with no negative results, material passed. Sensitization testing was conducted with no negative results, material passed. Irritation testing was conducted with no negative results, material passed Testing on file with no negative results as required by the ISO10993 standard for a material with $\leq$ 24hr patient exposure.
--------------------------	--	---

K180567/S001

March 12, 2018

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center WO66-0609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

FDA/CDRH/DCC

MAR 15 2018

RECEIVED

1499 Delp Drive

Harleysville, PA 19438

Tel: 215-256-4201

Reference: K180567, C3 Wave System – March 12th, 2018 RTA
To Whom It May Concern,

(b)(4) Deficiencies

(b)(4) Deficiencies

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4) Draft

(b)(4)

BIOBURDEN TEST REPORT

Procedure Reference: (b)(4)

(b)(4)

WO#:

(b)(4)

Page 1 of 1

Date Received: 10Jul2017

Customer: Medcomp
1499 Delp Drive
Harleysville, PA 19438

Product: C3 Accessory Pack Drape
Cat / Part #: (b)(4)
Lot #:

(b)(4)