June 14, 2019

Medical Components, Inc. (dba MedComp)
Courtney Nix
Regulatory Affairs Director, North America and Europe
1499 Delp Drive
Harleysville, PA 19438

Re: K183219
Trade/Device Name: Trio-CT™ Triple Lumen Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: NIE
Dated: May 16, 2019
Received: May 17, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. However, you are responsible to determine that the medical devices you use as components in the kits/trays have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kits/trays. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

In addition, we have determined that your device kits contain Lidocaine and Chloroprep which are subject to regulation as drugs.

Our substantially equivalent determination does not apply to the drug components of your device. We recommend you first contact the Center for Drug Evaluation and Research before marketing your device with the drug components. For information on applicable Agency requirements for marketing these drugs, we suggest you contact:

Director, Division of Drug Labeling Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857
(301) 594-0101

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Carolyn Y. Neuland, Ph.D.
Assistant Division Director
DHT3A: Division of Renal, Gastrointestinal,
Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183219

Device Name

Trio-CT™ Triple Lumen Catheter

Indications for Use *(Describe)*

The Trio-CT™ Triple Lumen Catheter is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis and apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring.

The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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

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Office of Chief Information Officer
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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."

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Section 6 **510(k) SUMMARY** **Traditional 510K**

A. Submitter Information

Submitter Name:	Medical Components Inc. (dba Medcomp®)
Address:	1499 Delp Drive Harleysville, PA 19438 USA
Registration Number:	2518902
Contact Person:	Courtney Nix Regulatory Affairs Manager, North America and EU
Date of Preparation:	11/19/2018

B. Subject Device

Trade Name:	Trio-CT™ Triple Lumen Catheter
Device:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
Regulation Description:	Blood Access Device and Accessories
Product Code:	NIE
Regulation Number:	876.5540
Class:	II
Review Panel:	Gastroenterology/Urology

C. Predicate Device

Predicate Trade Name:	MEDCOMP® T-3 CT
510(k) Number:	K123292
510(k) Holder:	Medical Components Inc.
Device:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
Regulation Description:	Blood Access Device and Accessories
Product Code:	NIE
Regulation Number:	876.5540
Class:	II
Review Panel:	Gastroenterology/Urology

D. Device Description

The Trio-CT™ Triple Lumen Catheter is a short-term (less than 30 days) dialysis catheter made of thermosensitive polyurethane. The catheter has three separate lumens allowing continuous blood flow. The venous (blue) and arterial (red) lumens may be used for hemodialysis and apheresis treatments. The middle (purple) lumen is independent from the two dialysis lumens, and may be used for intravenous therapy, power injection of contrast

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media, central venous pressure monitoring, blood draws and infusion of medications. The attachable suture wing can be used to provide additional catheter securement and to minimize movement at the exit site.

E. Indications For Use

The Trio-CT™ Triple Lumen Catheter is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis and apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring.

The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection of contrast media.

F. Intended Use

The Trio-CT™ Triple Lumen Catheter is a hemodialysis catheter that also has power injection, infusion and pressure monitoring capabilities through one designated lumen

G. Comparison to Predicate Device(s):

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	**Subject Device** Trio-CT™ Triple Lumen Catheter	**Predicate Device** T3 CT (K123292)
Prescription	Prescription Use	Prescription Use
Indications for Use	The Trio-CT™ Triple Lumen Catheter is indicated for use in attaining short-term (less than 30 days) vascular access for hemodialysis and apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring. The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection	The Medcomp® T3 CT catheter is a triple lumen catheter indicated for use in attaining short-term vascular access for hemodialysis, apheresis. The third internal lumen is intended for infusion, power injection of contrast media and central venous pressure monitoring. The catheter is intended to be inserted in the jugular, femoral or subclavian vein as required. The maximum recommended infusion rate is 5ml/sec for power injection

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<table>
<tr><td></td><td>of contrast media.</td><td>of contrast media.</td></tr>
<tr><td>Definition (From Product Code)</td><td>Short-term (< 30 days) central venous access for hemodialysis and apheresis, with a third lumen for infusion.</td><td>Short-term (< 30 days) central venous access for hemodialysis and apheresis, with a third lumen for infusion.</td></tr>
<tr><td>Location of Use</td><td>Hospital and/or Dialysis Center</td><td>Hospital and/or Dialysis Center</td></tr>
<tr><td>French Size</td><td>13.5F</td><td>15.5F</td></tr>
<tr><td>Lengths</td><td>12cm, 15cm, 20cm, 24cm, and 30cm</td><td>15cm, 20cm, 24cm, 28cm, and 32cm</td></tr>
<tr><td>Duration of Use</td><td>Short Term</td><td>Short Term</td></tr>
<tr><td>Sterilization Method</td><td>EO Sterilized</td><td>EO Sterilized</td></tr>
<tr><td>Number of Lumens</td><td>Three</td><td>Three</td></tr>
<tr><td>Patient Population</td><td>Adult</td><td>Adult</td></tr>
<tr><td>Insertion Site</td><td>Jugular, femoral or subclavian vein</td><td>Jugular, femoral or subclavian vein</td></tr>
<tr><td>Priming Volume (cc)</td><td>
<table>
<tr><th>Length</th><th>Center</th><th>Arterial</th><th>Venous</th></tr>
<tr><td>12cm</td><td>0.4</td><td>1.2</td><td>1.2</td></tr>
<tr><td>15cm</td><td>0.4</td><td>1.3</td><td>1.3</td></tr>
<tr><td>20cm</td><td>0.5</td><td>1.5</td><td>1.5</td></tr>
<tr><td>24cm</td><td>0.5</td><td>1.6</td><td>1.6</td></tr>
<tr><td>30cm</td><td>0.6</td><td>1.9</td><td>1.9</td></tr>
</table>
</td><td>
<table>
<tr><th>Length</th><th>Center</th><th>Arterial</th><th>Venous</th></tr>
<tr><td>15cm</td><td>0.4</td><td>1.4</td><td>1.5</td></tr>
<tr><td>20cm</td><td>0.5</td><td>1.6</td><td>1.7</td></tr>
<tr><td>24cm</td><td>0.5</td><td>1.7</td><td>1.8</td></tr>
<tr><td>28cm</td><td>0.6</td><td>1.9</td><td>2.0</td></tr>
<tr><td>32cm</td><td>0.7</td><td>2.1</td><td>2.2</td></tr>
</table>
</td></tr>
</table>

H. Bench/Performance Data/ Non-Clinical Testing:

Standard	Standard Title	Revision/Date	Performance Testing
ISO 10555-1	Intravascular catheters -- sterile and single-use intravascular catheters -- part 1: general requirements.	Second Edition 2013-06-15	Air Leak, Liquid Leak, Peak Tensile Force, Gravity Flow, Power Injection
ISO 11607-1	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier systems and packaging systems [including: amendment 1 (2014)].	First Edition 2006-04-15	Shipping and Shelf Life testing

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ISO 11607-2	Packaging for terminally sterilized medical devices - part 2: validation requirements for forming, sealing and assembly processes [including: amendment 1 (2014)].	First Edition 2006-04-15	Shipping and Shelf Life testing
ISO 594-1	conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 1: general requirements.	First edition 1986-06-15,	Gauging
ISO 594-2	Conical fittings with a 6% (luer) taper for syringes, needles and certain other medical equipment - part 2: lock fittings.	Second Edition 1998-09-01	Liquid Leakage Air Leakage Separation Force Unscrewing Torque Ease of Assembly Resistance to Overriding Stress Cracking

I. Biocompatibility

The biocompatibility evaluation for the Trio-CT™ Triple Lumen Catheter was conducted in accordance with the FDA guidance document: Use of International Standard ISO-10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing Within a Risk Management Process" and International Standard ISO 10993-1 "Biocompatibility Evaluation of Medical Devices – Part 1 Evaluation and Testing Within a Risk Management Process", as recognized by the FDA. The Trio-CT™ Triple Lumen Catheter met the biocompatibility requirements for externally communicating device with tissue and circulating blood contact for a prolonged (<30 days) duration. The biological endpoints that were met as are follows:

CYTOTOXICITY

- ISO 10993-5 *Biological Evaluation of Medical Devices – Part 5: Tests for In Vitro Cytotoxicity '*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <87>, Biological Reactivity Tests, In Vitro

SENSITIZATION

- ISO 10993-10 *Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*
- OECD 406 *Guideline for Testing of Chemical, Test No. 406, Skin Sensitization*

IRRITATION

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

ACUTE SYSTEMIC TOXICITY

- ISO 10993-11 *Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <151>, Pyrogen test

SUBCHRONIC TOXICITY

- ISO 10993-11 *Biological Evaluation of Medical Devices – Part 11: Test for Systemic Toxicity*
- OECD 407 *Guidelines for the Testing of Chemical, Test No. 407, Repeated Dose 28-Day Oral Toxicity Study in Rodents*

GENOTOXICITY

- ISO 10993-3 *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity*
- OECD 471 *Guidelines for Testing of Chemicals, Test No. 471, Bacterial Reverse Mutation Test*
- OECD 490 *Guidelines for the Testing of Chemicals, Test No. 490, In Vitro Mammalian Cell Gene Mutation Tests Using the Thymidine Kinase Gene*

IMPLANTATION

- ISO 10993-6 *Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <88>, Biological Reactivity Tests, In Vivo, Implantation Test, Table 6: Evaluation of Encapsulation in the Implantation Test

HEMOCOMPATIBILITY

- ASTM F756 *Standard Practice for Assessment of Hemolytic Properties of Materials*
- ISO 10993-4 *Biological Evaluation of Medical Devices – Part 4 Selection of Tests for Interactions with Blood*

J. Summary of Substantial Equivalence

In conclusion, the proposed device, Trio-CT™ Triple Lumen Catheter, is considered substantially equivalent to the predicate device, T3 CT (K123292) as demonstrated through non-clinical testing performed.