July 5, 2018

Medical Components Inc. (Dba Medcomp)
Courtney Nix
Regulatory Affairs Manager, North America and Europe
1499 Delp Drive
Harleysville, PA 19438

Re: K181175
Trade/Device Name: 12F Tri-Flow Triple Lumen Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: NIE
Dated: April 18, 2018
Received: May 2, 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. However, you are responsible to determine that the medical devices you use as components in the kit 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 kit/tray. 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 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,

Gema Gonzalez -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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

510(k) Number *(if known)*
K181175

Device Name
12F Tri-Flow Triple Lumen Catheter

Indications for Use *(Describe)*
The 12F Tri-Flow Triple Lumen Catheter is indicated for use in attaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian vein or femoral vein as required. The 12F Tri-Flow Triple Lumen Catheter is intended to be used less than (30) days.

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.

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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 Tel (215) 256-4201 X 2285 Fax (215) 256-9191
Registration Number:	2518902
Contact Person:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager, North America and Europe
Date of Preparation:	04/18/2018

B. Subject Device

Trade Name:	12F Tri-Flow Triple Lumen Catheter
Device:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
Regulation Description:	Blood Access Device and Accessories
Product Code:	NIE
21 CFR Regulation:	876.5540
Class:	2
Review Panel:	Gastroenterology/Urology

C. Predicate Device

Predicate Trade Name:	MEDCOMP® T-3
510(k) Number:	K033570
510(k) Holder:	Medical Components Inc.
Device:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
Regulation Description:	Blood Access Device and Accessories
Product Code:	NIE
21 CFR Regulation:	876.5540
Class:	2
Review Panel:	Gastroenterology/Urology

D. Reference Device

Predicate Trade Name:	T-3 CT
510(k) Number:	K123292
510(k) Holder:	Medical Components Inc.

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Device:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted
Regulation Description:	Blood Access Device and Accessories
Product Code:	NIE
21 CFR Regulation:	876.5540
Class:	2
Review Panel:	Gastroenterology/Urology

E. Device Description:

The 12F Tri-Flow Triple Lumen Catheter is a short term 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 (clear) lumen is independent from the two dialysis lumens, and may be used for intravenous therapy, blood draws and infusion of medications.

F. Indications For Use:

The 12F Tri-Flow Triple Lumen Catheter is indicated for use in attaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate insertion sites include subclavian vein or femoral vein as required. The 12F Tri-Flow Triple Lumen Catheter is intended to be used less than (30) days.

G. Intended Use

The 12F Tri-Flow Triple Lumen Catheter with a third internal lumen for Infusion is indicated for use in attaining short-term vascular access for hemodialysis and apheresis. The third lumen allows infusion of fluids, medications, and/or when nutritional therapy is prescribed.

H. Comparison to Predicate Device(s):

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	Subject Device 12F Tri-Flow Triple Lumen Catheter	Predicate Device Medcomp® T-3 (K033570)
Prescription	Prescription Use	Prescription Use
Indications for Use	The 12F Tri-Flow Triple Lumen Catheter is indicated for use in attaining Short-Term vascular access for Hemodialysis and Apheresis. It may be inserted percutaneously and is primarily placed in the internal jugular vein of an	The Medcomp® T-3 is indicated for use in attaining Short-Term vascular access for Hemodialysis, Apheresis, and Infusion.It may be inserted percutaneously and is primarily placed in the internal jugular vein of an adult patient. Alternate

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<table>
<tr><td></td><td>adult patient. Alternate insertion sites include subclavian vein or femoral vein as required. The 12F Tri-Flow Triple Lumen Catheter is intended to be used less than (30) days.</td><td>insertion sites include the subclavian vein. The Medcomp® T-3 is intended to be used less than (30) days.</td></tr>
<tr><td>Tip Design</td><td>Step</td><td>Step</td></tr>
<tr><td>General Purpose of Device</td><td>Hemodialysis and Apheresis</td><td>Hemodialysis and Apheresis</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>12F</td><td>15F</td></tr>
<tr><td>Lengths</td><td>Curved Extensions: 15 and 20cm
Straight Extension: 15, 20, & 24 cm</td><td>Curved Extensions: 15 and 20cm
Straight Extension: 15, 20, & 24 cm</td></tr>
<tr><td>Duration of Use</td><td>Short Term (<30 Days)</td><td>Short Term</td></tr>
<tr><td>Catheter Type</td><td>Hemodialysis</td><td>Hemodialysis</td></tr>
<tr><td>Sterilization</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>Internal jugular vein, subclavian vein, and femoral vein*</td><td>Internal jugular vein and subclavian vein</td></tr>
<tr><td>Proper Placement of Tip</td><td>The distal tip should be located just before the junction of the superior vena cava and the right atrium</td><td>The distal venous tip should be located just before the junction of the superior vena cava and the right atrium.</td></tr>
<tr><td>Priming Volume (cc)</td><td>
<table>
<tr><td colspan="4">Curved</td></tr>
<tr><td>Length</td><td>P</td><td>D</td><td>M</td></tr>
<tr><td>15cm</td><td>1.26</td><td>0.40</td><td>1.27</td></tr>
<tr><td>20cm</td><td>1.38</td><td>0.46</td><td>1.45</td></tr>
<tr><td colspan="4">Straight</td></tr>
<tr><td>Length</td><td>P</td><td>D</td><td>M</td></tr>
<tr><td>15cm</td><td>1.06</td><td>0.35</td><td>1.07</td></tr>
<tr><td>20cm</td><td>1.20</td><td>0.45</td><td>1.26</td></tr>
<tr><td>24cm</td><td>1.23</td><td>0.48</td><td>1.34</td></tr>
</table>
</td><td>
<table>
<tr><td>Length</td><td>P</td><td>D</td></tr>
<tr><td>15cm</td><td>1.5</td><td>1.5</td></tr>
<tr><td>20cm</td><td>1.7</td><td>1.7</td></tr>
<tr><td>24cm</td><td>1.8</td><td>1.8</td></tr>
<tr><td>32cm</td><td>2.1</td><td>2.1</td></tr>
</table>
</td></tr>
</table>

*The reference device, T-3 CT (K123292), is used being used for the femoral insertion site.

I. **Bench/Performance Data/ Non-Clinical Testing:**

Standard	Standard Title	Revision/ Date	Performance Testing
ISO 10555-1	Intravascular	Second Edition	Air Leak, Catheter

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	catheters -- sterile and single-use intravascular catheters -- part 1: general requirements.	2013-06-15	Leak, Extension-Hub, Extrusion-Hub, Gravity Flow
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
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	Second Edition 1998-09-01	Liquid Leakage Air Leakage Separation Force Unscrewing Torque Ease of Assembly Resistance to

	medical equipment - part 2: lock fittings.		Overriding Stress Cracking

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J. Biocompatibility

The biocompatibility evaluation for the 12F Tri-Flow 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 12F Tri-Flow Triple Lumen Catheter met the biocompatibility requirements for an externally communicating device with tissue and circulating blood contact for prolong (>24 h to 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
- 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*

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- 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*

K. Summary of Substantial Equivalence

In conclusion, the proposed device, 12F Tri-Flow Triple Lumen Catheter, is considered substantially equivalent to the predicate device, Medcomp® T-3 (K033570) as demonstrated through non-clinical testing performed and T-3 CT (K123292) for the femoral insertion site.