November 16, 2023

Medical Components Inc. (Dba MedComp)
Danielle McKinney
Regulatory Affairs Associate II
1499 Delp Drive
Harleysville, Pennsylvania 19438

Re: K232945
Trade/Device Name: Trio-CT® Triple Lumen Catheter w/ Curved Extensions
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: NIE
Dated: September 20, 2023
Received: September 20, 2023

Dear Danielle McKinney:

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 (the 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 available 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 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Gema Gonzalez -S

Maura Rooney, MS
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K232945

Device Name

Trio-CT® Triple Lumen Catheter w/ Curved Extensions

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.

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U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center (DCC) – W066-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

510(k) Summary
Traditional 510(k): Original

1. Submitter Information:

510(k) Submitted By:	Medical Components Inc. (Dba MedComp) 1499 Delp Drive Harleysville, PA 19438 United States of America
Primary Correspondent:	Danielle McKinney, Regulatory Affairs Associate II regulatory@medcompnet.com 843-467-5661
Date Prepared:	September 20, 2023

2. Subject Device Information:

Trade Name:	Trio-CT® Triple Lumen Catheter w/ Curved Extensions
Common Name:	Triple Lumen Catheter
Regulation Name:	Blood Access Device and Accessories, 21 CFR 876.5540
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology
Product Code:	NIE

3. Predicate Device Information:

Trade Name (predicate):	Trio-CT™ Triple Lumen Catheter
Common Name (predicate):	Triple Lumen Catheter
Classification Regulation:	Catheter, Hemodialysis, Triple Lumen, Non-Implanted, 21 CFR 876.5540
Device Class:	Class II
Classification Panel:	Gastroenterology/Urology
Product Code:	NIE
Predicate 510(k) Number:	510(k) K183219
Predicate 510(k) Owner:	Medical Components Inc. (Dba MedComp)

4. 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 media, central venous pressure monitoring, blood draws and infusion of medications. The catheter is available with straight or curved extensions in a variety of lengths to accommodate physician preference and clinical needs. The attachable suture wing can be used to provide additional catheter securement and to minimize movement at the exit site.

5. 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.

6. Summary of Technological Characteristics

The subject device has similar technological characteristics as the predicate device. The Trio-CT® Triple Lumen Catheters facilitate hemodialysis, intravenous administration of fluids or medications, and power injection of contrast media in patients in whom immediate central venous vascular access for short-term hemodialysis is deemed necessary based on the direction of a qualified, licensed physician. The catheter is not intended for use in pediatric patients. The Trio-CT® Triple Lumen Catheters utilize a symmetric/tapered tip design which facilitates insertion without a peelable introducer. The Trio-CT® Triple Lumen Catheters are made from medical-grade chemically-stable materials and are provided sterile and non-pyrogenic. The catheters can be inserted via the internal jugular vein, femoral vein or subclavian vein. While there are differences in the anatomic reference points utilized for properly identifying the insertion site and risks associated with each site, once the insertion site is identified, the implantation process utilizes the Seldinger insertion method to place the catheter. Regardless of insertion point selected, Trio-CT® Triple Lumen Catheters are to be inserted, manipulated and removed by a qualified, licensed physician or other qualified health care professional under direction of a physician utilizing strict aseptic technique. Based on the similarity of these technological characteristics, there are no changes that affect the safety or effectiveness of the Trio-CT® Triple Lumen Catheter w/ Curved Extensions.

7. Substantial Equivalence Discussion

The Substantial Equivalence Comparison Table (**Table 2**) below provides evidence to facilitate the substantial equivalence determination between the Trio-CT® Triple Lumen Catheter w/ Curved Extensions to the predicate device Trio-CT™ Triple Lumen Catheter.

Table 2: Substantial Equivalence Comparison

<table>
<tr><th>Description</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Device Trade Name</td><td>Trio-CT® Triple Lumen Catheter w/ Curved Extensions</td><td>Trio-CT™ Triple Lumen Catheter</td></tr>
<tr><td>510(k) submitter/holder</td><td>Medical Components Inc. (Dba MedComp)</td><td>Medical Components Inc. (Dba MedComp)</td></tr>
<tr><td>510(k) Number</td><td>K#######</td><td>K183219</td></tr>
<tr><td>Indications for Use</td><td>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.</td><td>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.</td></tr>
<tr><td>Prescription/Over-the-Counter Use</td><td>Prescription Use</td><td>Prescription Use</td></tr>
<tr><td>Target Population</td><td>Adult</td><td>Adult</td></tr>
<tr><td>Duration of Use</td><td>Short Term</td><td>Short Term</td></tr>
<tr><td>Sterilization Method</td><td>1x and/or 2x EO Sterilized</td><td>1x and/or 2x EO Sterilized</td></tr>
<tr><td colspan="3">Technical Specifications</td></tr>
<tr><td>Catheter French Size</td><td>13.5F</td><td>13.5F</td></tr>
<tr><td>Inner Diameters</td><td>Venous – 0.088” nominal
Arterial – 0.088” nominal
Infusion – 0.042” nominal</td><td>Venous – 0.088” nominal
Arterial – 0.088” nominal
Infusion – 0.042” nominal</td></tr>
<tr><td>Number of Lumens</td><td>Three (3)</td><td>Three (3)</td></tr>
<tr><td>Catheter Lengths</td><td>12cm, 15cm, 20cm and 24cm</td><td>12cm, 15cm, 20cm, 24cm and 30cm</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 cc</td><td>1.4 cc</td><td>1.4 cc</td></tr>
<tr><td>15cm</td><td>0.4 cc</td><td>1.5 cc</td><td>1.5 cc</td></tr>
<tr><td>20cm</td><td>0.5 cc</td><td>1.7 cc</td><td>1.7 cc</td></tr>
<tr><td>24cm</td><td>0.5 cc</td><td>1.9 cc</td><td>1.9 cc</td></tr>
</table>
</td><td>
<table>
<tr><th>Length</th><th>Center</th><th>Arterial</th><th>Venous</th></tr>
<tr><td>12cm</td><td>0.4 cc</td><td>1.2 cc</td><td>1.2 cc</td></tr>
<tr><td>15cm</td><td>0.4 cc</td><td>1.3 cc</td><td>1.3 cc</td></tr>
<tr><td>20cm</td><td>0.5 cc</td><td>1.5 cc</td><td>1.5 cc</td></tr>
<tr><td>24cm</td><td>0.5 cc</td><td>1.6 cc</td><td>1.6 cc</td></tr>
<tr><td>30cm</td><td>0.6 cc</td><td>1.9 cc</td><td>1.9 cc</td></tr>
</table>
</td></tr>
<tr><td>Power Injection Pressure (psi)</td><td>
<table>
<tr><th>Max Indicated Power Injection Flow-Rate</th><th>Average Max Catheter Pressure During Max Indicated Power Injection Flow Rate</th><th>Average Max Burst Pressure</th><th>Range of Max Burst Pressures</th></tr>
<tr><td>5 ml/sec</td><td>92 psi</td><td>314 psi</td><td>277-425 psi</td></tr>
</table>
</td><td>
<table>
<tr><th>Max Indicated Power Injection Flow-Rate</th><th>Average Max Catheter Pressure During Max Indicated Power Injection Flow Rate</th><th>Average Max Burst Pressure</th><th>Range of Max Burst Pressures</th></tr>
<tr><td>5 ml/sec</td><td>84 psi</td><td>420 psi</td><td>332-446 psi</td></tr>
</table>
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<table>
<tr><th>Description</th><th>Subject Device</th><th>Predicate Device</th></tr>
<tr><td>Flow (ml/min) vs Pressure (mmHg)</td><td>
<table>
<tr><th colspan="2">Flow Rate (ml/min)</th><th>200</th><th>300</th><th>400</th></tr>
<tr><td rowspan="2">12CM</td><td>Venous</td><td>20</td><td>41</td><td>61</td></tr>
<tr><td>Arterial</td><td>-29</td><td>-44</td><td>-69</td></tr>
<tr><td rowspan="2">15CM</td><td>Venous</td><td>21</td><td>40-</td><td>59</td></tr>
<tr><td>Arterial</td><td>-30</td><td>-45</td><td>-70</td></tr>
<tr><td rowspan="2">20CM</td><td>Venous</td><td>30</td><td>45</td><td>72</td></tr>
<tr><td>Arterial</td><td>-30</td><td>-49</td><td>-74</td></tr>
<tr><td rowspan="2">24CM</td><td>Venous</td><td>30</td><td>46</td><td>71</td></tr>
<tr><td>Arterial</td><td>-30</td><td>-50</td><td>-80</td></tr>
</table>
</td><td>
<table>
<tr><th colspan="2">Flow Rate (ml/min)</th><th>200</th><th>300</th><th>400</th></tr>
<tr><td rowspan="2">12CM</td><td>Venous</td><td>20</td><td>30</td><td>51</td></tr>
<tr><td>Arterial</td><td>-21</td><td>-40</td><td>-60</td></tr>
<tr><td rowspan="2">15CM</td><td>Venous</td><td>20</td><td>40</td><td>63</td></tr>
<tr><td>Arterial</td><td>-26</td><td>-46</td><td>-70</td></tr>
<tr><td rowspan="2">20CM</td><td>Venous</td><td>21</td><td>40</td><td>62</td></tr>
<tr><td>Arterial</td><td>-30</td><td>-50</td><td>-70</td></tr>
<tr><td rowspan="2">24CM</td><td>Venous</td><td>30</td><td>50</td><td>76</td></tr>
<tr><td>Arterial</td><td>-33</td><td>-50</td><td>-80</td></tr>
<tr><td rowspan="2">30CM</td><td>Venous</td><td>30</td><td>51</td><td>84</td></tr>
<tr><td>Arterial</td><td>-33</td><td>-59</td><td>-90</td></tr>
</table>
</td></tr>
<tr><td colspan="3">Principles of Operation</td></tr>
<tr><td>Insertion Site</td><td>Jugular, femoral or subclavian vein</td><td>Jugular, femoral or subclavian vein</td></tr>
</table>

8. Summary of Non-Clinical Testing and Standards

8.1 Biocompatibility

A biocompatibility evaluation was performed in accordance with the FDA Guidance *'Use of International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process"'.*

Based on this evaluation, the following tests were conducted:

- ISO Muscle Implantation Study in Rabbits - 4 Weeks
- USP Rabbit Pyrogen Study, Material Mediated
- ASTM Hemolysis Study
- SC5b-9 Complement Activation Assay
- ISO Guinea Pig Maximization Sensitization Test
- ISO Intracutaneous Study in Rabbits
- Cytotoxicity Study Using the ISO Elution Method
- ISO Acute Systemic Toxicity Study in Mice
- ISO Systemic Toxicity Study in the Rat, Repeated Parenteral Administration of Two Extracts, 28 Days
- Bacterial Reverse Mutation Study
- Genotoxicity: Mouse Lymphoma Assay
- Infrared Spectroscopy
- Mechanical Hemolysis Testing of Triple Lumen Catheters
- In Vivo GLP 30 Day Thromboresistance Study in Sheep- Jugular Vein

8.2 Performance Testing

Design validation performance testing was leveraged from the predicate device manufactured by Medical Components, Inc. Design verification performance testing was completed to confirm performance criteria of the subject device. Clinical testing was not required nor performed to support the substantial equivalence of these devices.

9. Conclusion

In conclusion, based on the non-clinical testing performed, the subject device Trio-CT® Triple Lumen Catheter w/ Curved Extensions is substantially equivalent to the predicate device Trio-CT™ Triple Lumen Catheter [510(k) K183219] and does not raise any concern for the safety and effectiveness of the subject device.