April 23, 2020

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

Re: K192807
Trade/Device Name: Duo-Flow Side x Side Double Lumen Catheter
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: II
Product Code: MPB
Dated: March 13, 2020
Received: March 16, 2020

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. 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.

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 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)*
K192807

Device Name
Duo-Flow Side x Side Double Lumen Catheter

Indications for Use *(Describe)*
The Duo-Flow Side x Side Double Lumen Catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion.

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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Medcomp®: Duo-Flow® Side x Side Double Lumen Catheter

Section 6 510(k) SUMMARY Traditional 510K

A. Submitter Information

Submitter Name:	Medical Components Inc. (dba Medcomp®)
Address:	1499 Delp Drive Harleysville, PA 19438
Registration Number:	2518902
Contact Person:	Courtney Nix Regulatory Affairs Director, North America and EU
Date of Preparation:	09/27/2019

B. Subject Device

Trade Name:	Duo-Flow® Side x Side Double Lumen Catheter
Device:	Catheter, Hemodialysis, Non-Implanted
Regulation Description:	Blood access device and accessories
Product Code:	MPB
Regulation Number:	876.5540
Class:	II
Review Panel:	Gastroenterology/Urology

C. Predicate Device

Predicate Trade Name:	Mahurkar™ Acute Dual Lumen Catheter
510(k) Number:	K955002
510(k) Holder:	Quinton, Inc.
Device:	Catheter, Hemodialysis, Non-Implanted
Regulation Description:	Blood access device and accessories
Product Code:	MPB
Regulation Number:	876.5540
Class:	II
Review Panel:	Gastroenterology/Urology

D. Device Description:

The Duo-Flow® Side x Side double lumen catheter is a radiopaque, polyurethane tube with two D-shaped lumina. The lumina can be distinguished by the color-coded luers:

- Red Adapter = proximal lumen
- Blue Adapter = distal lumen

The proximal lumen provides "arterial" outflow from the patient; the distal lumen provides "venous" return.

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The catheter comes in a variety of sizes and is offered with curved or straight extensions.

E. Indications for Use:

The Duo-Flow® Side x Side Double Lumen Catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion.

F. Comparison to Predicate Device(s):

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	**Subject Device** Duo-Flow® Side x Side Double Lumen Catheter	**Predicate Device** Mahurkar™ Acute Dual Lumen Catheter (K955002)
Prescription	Prescription Use	Prescription Use
Indications for Use	The Duo-Flow® Side x Side Double Lumen Catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion	The catheter is intended for short-term central venous access for hemodialysis, apheresis, and infusion.
Definition (From Product Code)	Short-term (< 30 days) central venous access for hemodialysis and apheresis.	Short-term (< 30 days) central venous access for hemodialysis and apheresis.
Location of Use	The operating room is the preferred location for insertion; however, bedside insertion is acceptable if sterile technique is followed.	The operating room is the preferred location for insertion; however, bedside insertion is acceptable if sterile technique is followed.
French Size	9F, 11F, and 12F	8F, 10F, 11.5F and 13.5F
Catheter Configuration	Straight and Curved Extensions	Straight, Curved Extensions, and Pre-Curved
Lengths	French Size: 9 — Length(s) (cm): 7.5, 10, 12, 15, 20 French Size: 11 — Length(s) (cm): 10, 12, 15, 20, 24 French Size: 12 — Length(s) (cm): 13, 15, 20, 24	French Size: 8F — Length(s) (cm): 9cm (Straight only), 12cm, 15cm French Size: 10 — Length(s) (cm): 12, 15, 19.5 French Size: 11.5 — Length(s) (cm): 13.5, 16, 19.5, 24 French Size: 13.5 — Length(s) (cm): 13.5, 16, 19.5, 24
Duration of Use	Short-term (less than 30 days)	Per K-DOQI guidelines: (1) Remove the catheter when no

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		longer needed, (2) Remove femoral catheters within 3-4 days, and (3) Replace subclavian and jugular catheters every 21 days.
Sterilization Method	EO	EO
Number of Lumens	2	2
Patient Population	Adult	Adult
Insertion Site	Subclavian, jugular or femoral	Subclavian, jugular or femoral
Kit Type	Convenience	Legally Marketed

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

Table 6.2: Applicable Standards and Performance 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
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	Transit 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	Transit and Shelf Life testing
ISTA 3A	Packaged products for parcel delivery system shipment 70 KG (150 lbs) or less	2008	Transit Testing
ISO 594-1	Conical fittings with a 6%	First edition	Gauging

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	(Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements	1986-06-15	
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

H. Biocompatibility

The biocompatibility evaluation for the Duo-Flow® Side x Side Double 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 Duo-Flow® Side x Side Double Lumen Catheter met the biocompatibility requirements for externally communicating medical device intended to primarily be in contact with circulating blood for a prolonged contact duration (>24 hours to less than 30 days). The biological endpoints that were met as are follows:

CYTOTOXICITY

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

SENSITIZATION

- ISO 10993-10:2010, *Biological Evaluation of Medical Devices* – Part 10: *Tests for Irritation and Skin Sensitization*

IRRITATION OR INTRACUTANEOUS REACTIVITY

- ISO 10993-10:2010, *Biological Evaluation of Medical Devices* – Part 10: *Tests for Irritation and Skin Sensitization*

SYSTEMIC TOXICITY

- ISO 10993-11:2006, *Biological Evaluation of Medical Devices* – Part 11: *Tests for Systemic Toxicity*

PYROGENICITY

- ISO 10993-11:2006, *Biological Evaluation of Medical Devices* – Part 11: *Tests for Systemic Toxicity, Annex F*

SUBACUTE TOXICITY

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- ISO 10993-11:2006, *Biological Evaluation of Medical Devices* – Part 11: *Tests for Systemic Toxicity*

GENOTOXICITY

- ISO 10993-3:2014, *Biological Evaluation of Medical Devices* – Part 3: *Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity*

IMPLANTATION

- ISO 10993-6:2016, *Biological Evaluation of Medical Devices* – Part 6: *Test for Local Effects After Implantation*

HEMOCOMPATIBILITY

- ASTM F576:2017, *Standard Practice for Assessment of Hemolytic Properties of Materials*
- ISO 10993-4:2002/A1:2006, *Biological Evaluation of Medical Devices* – Part 4: *Selection of Tests for Interactions with Blood*
- ISO 10993-4:2017, *Biological Evaluation of Medical Devices* – Part 4: *Selection of Tests for Interactions with Blood*

OTHER

- ISO 10993-18, 2005, *Biological Evaluation of Medical Devices*, Part 18: *Chemical Characterization of Materials*

I. Summary of Substantial Equivalence

Based on the indications for use, design, safety and performance testing, the proposed device, Duo-Flow® Side x Side Double Lumen Catheter, raises no new questions of effectiveness compared to the predicate device and is substantially equivalent to the predicate device, Mahurkar™ Acute Dual Lumen Catheter (K955002).