September 3, 2020

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

Re: K202176
Trade/Device Name: Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: August 3, 2020
Received: August 4, 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)*
K202176

Device Name
Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes

Indications for Use *(Describe)*
The Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.

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** **Special 510K**

K202176

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 Regulatory Affairs Director, North America and Europe
Date of Preparation:	07/31/2020

B. Subject Device

Trade Name:	Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes
Device:	Catheter, Hemodialysis, Implanted
Product Code:	MSD
Regulation Description:	Blood access device and accessories
Regulation Number:	21 CFR 876.5540
Class:	II (Special Controls)
Regulation Medical Specialty and Review Panel:	Gastroenterology/Urology

C. Predicate Device

510(k) Number:	K171618 & K173667
510(k) Holder:	Medcomp®
Trade Name:	Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes

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Regulation Medical Specialty and Review Panel:	Gastroenterology/Urology

D. Device Description:

The Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes is a chronic, 15.5 French, dual lumen, radiopaque catheter made of polyurethane. It has a polyester retention cuff and two female luer adapters. The retention cuff promotes tissue ingrowth to anchor the catheter in the subcutaneous tunnel. The luer adapters are identical in color to indicate the reversibility of this catheter. This catheter features symmetrical side channels with a distal tip configuration designed to separate the intake flow from the output flow in both directions.

E. Indications For Use:

The Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and apheresis. It may be inserted percutaneously or by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.

F. Intended Use:

Long term, greater than 30 days, vascular access for Hemodialysis and Apheresis treatments.

G. Comparison to Predicate Device(s):

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	Subject Device Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes	Predicate Device Symetrex® Long Term Hemodialysis Catheter (K171618) & Symetrex® Long Term Hemodialysis Catheter with Sideholes (K173667)
Prescription	Prescription Use	Prescription Use

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Indications for Use	The Symetrex® Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and aphersis. It may be inserted percutaneously of by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.	The Symetrex® Long Term Hemodialysis Catheter with Sideholes is a symmetric tip dual lumen catheter designed for chronic hemodialysis and aphersis. It may be inserted percutaneously of by cut down. Catheters with greater than 37cm implant length are indicated for femoral placement.
Catheter O.D.	15.5Fr	15.5Fr
Lengths	19cm-42cm	19cm-42cm
Duration of Use	Long Term	**Long Term**
Sterilization Method	EO	EO
Number of Lumens	2	2
Patient Population	Adult	Adult

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

The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes, is equivalent to the predicate device, Symetrex® Long Term Hemodialysis Catheter (K171618) & Symetrex® Long Term Hemodialysis Catheter with Sideholes (K173667). The performance testing was performed in accordance with the following standards:

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, Catheter Leak, Extension-Hub, Extrusion-Hub, Gravity Flow
ISO 11607-1	Packaging for terminally sterilized medical devices - part 1: requirements for materials, sterile barrier	First Edition 2006-04-15	Shipping and Shelf Life testing

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	systems and packaging systems [including: amendment 1 (2014)].		
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 80369-7	ISO 80369-7 First edition 2016-10-15 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications	First Edition 2016-10-15	Gauging

I. Biocompatibility

Biocompatibility was performed for the Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes per ISO 10993-1 for a blood implant device with permanent exposure (i.e. > 30 days). Biocompatibility was performed on the final, finished device. The biological end points include:

- Hemocompatibility:
  - ISO 10993-4 *Biological Evaluation Of Medical Devices - Part 4: Selection Of Tests For Interaction With Blood*
  - ASTM F 756-08, *Standard Practice for Assessment of Hemolytic Properties of Materials, 2008*

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

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- Cytotoxicity:
  - AAMI / ANSI / ISO 10993-5: *Biological evaluation of medical devices - part 5: tests for in vitro cytotoxicity.*

- Irritation/Intracutaneous:
  - 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*

- Implantation:
  - ISO 10993-6 *Biological Evaluation of Medical Devices - Part 6: Tests for Local Effects after Implantation.*
  - ASTM F763-04 *Standard Practice For Short-Term Screening of Implant Materials.*
  - ASTM F981-04 *Standard Practice For Assessment of Compatibility of Biomaterials for Surgical Implants With Respect To Effect of Materials on Muscle and Bone.*

- Additional Testing:
  - ISO 10993-18 *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*
  - ASTM D4128-06 Standard Guide for Identification of Quantitation of Organic Compounds in Water by Combined Gas Chromatography and Electron Impact Mass Spectrometry
  - ASTM D1971-11 Standard Practices for Digestion of Water Samples for Determination of Metals by Flame Atomic Absorption, Graphite Furnace Atomic Absorption, Plasma Emission Spectroscopy, or Plasma Mass Spectroscopy
  - ISO 10993-17 *Biological Evaluation of Medical Devices – Part 17: Establishment of Allowable Limits for Leachable Substances*

J. Cybersecurity and Wireless Information

The Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes is not an electrical device. There is no cybersecurity and wireless information.

K. Summary of Substantial Equivalence

In conclusion, the proposed device, Symetrex® Long Term Hemodialysis Catheter & Symetrex® Long Term Hemodialysis Catheter with Sideholes, is considered substantially equivalent to the predicate device, Symetrex® Long Term Hemodialysis (K171618) & Symetrex® Long Term Hemodialysis Catheter with Sideholes (K173667), as demonstrated through non-clinical testing performed.