November 16, 2017

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

Re: K171618
Trade/Device Name: Symetrex Long Term Hemodialysis Catheter
Regulation Number: 21 CFR§ 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: MSD
Dated: October 6, 2017
Received: October 11, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Benjamin R. Fisher -S

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)*
K171618

Device Name
Symetrex Long Term Hemodialysis Catheter

Indications for Use *(Describe)*
The Symetrex™ Long Term Hemodialysis Catheter is a symmetric tip dual lumen catheter designed for chronic hemodialysis and aphersis. 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.

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

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Medcomp®: Symetrex™ Long Term Hemodialysis Catheter

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

K171618

1. **Submitter Information:**

Submitter:	Medical Components Inc. Dba Medcomp® 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201, x 2285 Fax: (215) 256-9191
Registration Number:	2518902
Contact:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager: North America and EU
Date Prepared:	05/30/2017

2. **Proposed or Subject Device Information:**

Trade Name:	Symetrex™ Long Term Hemodialysis Catheter
Device:	Catheter, Hemodialysis, Implanted
Product Code:	MSD
Regulation Description:	Blood access device and accessories
C.F.R. Section:	21 CFR 876.5540
Class:	II (Special Controls)
Regulation Medical Specialty and Review Panel:	Gastroenterology/Urology

3. **Predicate Device Information:**

510(k) Number:	K140884
510(k) Holder:	Medcomp®
Trade Name:	Symetrex™ Long Term Hemodialysis Catheter
Device:	Catheter, Hemodialysis, Implanted
Product Code:	MSD

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Regulation Description:	Blood access device and accessories
C.F.R Section:	21 CFR 876.5540
Class:	II (Special Controls)
Regulation Medical Specialty and Review Panel:	Gastroenterology/Urology

4. Device Description:

The Symetrex™ Long Term Hemodialysis Catheter 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.

5. Indications for Use:

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

6. **Intended Use:**

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

7. Comparison to Predicate Devices:

Symetrex™ Long Term Hemodialysis Catheter is substantially equivalent to the predicate device, Symetrex™ Long Term Hemodialysis Catheter (K140884), in terms of indications for use, intended use, anatomical location, basic design, performance, manufacturing process and method of sterilization.

The difference or changes between the Symetrex™ Long Term Hemodialysis Catheter and the predicate, Symetrex™ Long Term Hemodialysis Catheter (K140884), are the revisions to the labeling (e.g. Instructions for Use), sterilization site, and expanding the componentry.

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Table 6.1: 510(K) Summary: Design Comparison Matrix

Device	**Proposed Device:** Symetrex™ Long Term Hemodialysis Catheter	**Predicate Device:** Symetrex™ Long Term Hemodialysis Catheter (K140884)
Design	Symmetric Tip, Dual Kidney Shaped Lumen Catheter	Symmetric Tip, Dual Kidney Shape Lumen Catheter
Lengths	19cm-42cm	19cm-42cm
Indications for Use	The Symetrex™ Long Term Hemodialysis Catheter 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 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
Sterilization Method	EO Sterilization	EO Sterilization
Materials	**Hub (Green)**: Carbothane w/ 20% BaSO4 **Lumen (White)**: Carbothane w/ 20% BaSO4 **Cuff**: Polyester Felt **Extension (Clear)**: Pellethane **Barbed Luer (Green)** : Isoplast **ID Ring (White with red ink):** ABS **ID Ring (White with blue ink):** ABS **Clamp (White):** Polypropylene	**Hub (Green)**: Carbothane w/ 20% BaSO4 **Lumen (White)**: Carbothane w/ 20% BaSO4 **Cuff**: Polyester Felt **Extension (Clear)**: Pellethane **Barbed Luer (Green)** : Isoplast **ID Ring (White with red ink):** ABS **ID Ring (White with blue ink):** ABS **Clamp (White):** Polypropylene
Components	Dilator, Stylet, Tunneler, Valved Introducer, and Guidewire	Dilator, Stylet, Valved Introducer and Tunneler

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<table>
<tr><td></td><td></td><td></td></tr>
<tr><td>Packaging Systems</td><td>Clamshell tray for catheters under 33cm

Translumbar tray for catheters for 33 cm and greater

Clamshell:
One unit gets a snap lid
one unit is sealed into a header bag
5 Header bags are placed in a shipping carton

Translumbar tray:
One unit gets a snap lid
One unit is sealed into a header bag.
5 units are placed into a shipping carton.</td><td>Symetrex Tray (Predicate)

One units gets a snap lid
One unit is sealed in a pouch
One sealed unit is placed into an SBS Shelf Box
15 are placed into a shipping carton</td></tr>
<tr><td>Performance Testing</td><td>Priming Volume:

<table><tr><td>Tip to Cuff Length</td><td>Lumen Volume</td></tr><tr><td>19cm</td><td>2.1cc</td></tr><tr><td>23cm</td><td>2.3cc</td></tr><tr><td>28cm</td><td>2.5cc</td></tr><tr><td>33cm</td><td>2.6cc</td></tr><tr><td>37cm</td><td>2.8cc</td></tr><tr><td>42cm</td><td>3.2cc</td></tr></table>
Recirculation:
Symetrex™ Long Term Hemodialysis Catheter has less than 1% recirculation in forward and reverse flow when tested in vitro.</td><td>Priming Volume:

<table><tr><td>Tip to Cuff Length</td><td>Lumen Volume</td></tr><tr><td>19cm</td><td>2.1cc</td></tr><tr><td>23cm</td><td>2.3cc</td></tr><tr><td>28cm</td><td>2.5cc</td></tr><tr><td>33cm</td><td>2.6cc</td></tr><tr><td>37cm</td><td>2.8cc</td></tr><tr><td>42cm</td><td>3.2cc</td></tr></table>
Recirculation:
Symetrex™ Long Term Hemodialysis Catheter has less than 1% recirculation in forward and reverse flow when tested in vitro.</td></tr>
</table>

8. 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, is equivalent to the predicate device, Symetrex™ Long Term Hemodialysis Catheter (K140884). The performance testing was performed in accordance with the following standards:

Table 6.2: Performance Standards

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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 systems and packaging systems [including: amendment 1 (2014)].	First Edition 2006-04-15	V-10712: 15.5F Symetrex Catheter – Shipping Tests – 32cm Clamshell Tray w/Packaging Envelope V-10713: 15.5F Symetrex Catheter – Shipping Test
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	V-10712: 15.5F Symetrex Catheter – Shipping Tests – 32cm Clamshell Tray w/Packaging Envelope V-10713: 15.5F Symetrex Catheter – Shipping Test
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)	Second Edition 1998-09-01	Liquid Leakage Air Leakage

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	taper for syringes, needles and certain other medical equipment - part 2: lock fittings.		Separation Force Unscrewing Torque Ease of Assembly Resistance to Overriding Stress Cracking

9. **Biocompatibility:**

Biocompatibility was performed for the Symetrex™ Long Term Hemodialysis Catheter per ISO 10993-1 for a blood implant device with prolonged exposure (i.e. > 24 hours < 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.*

- 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*

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- 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*

10. Summary of Substantial Equivalence:

In conclusion, the proposed device, Symetrex™ Long Term Hemodialysis Catheter, is considered substantially equivalent to the predicate device, Symetrex™ Long Term Hemodialysis (K140884) as demonstrated through non-clinical testing performed.