December 15, 2017

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

Re: K171483
Trade/Device Name: Arch-Flo CT Midline
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: PND
Dated: September 1, 2017
Received: November 17, 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. 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,

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K171483

Device Name

Arch-Flo CT Midline

Indications for Use *(Describe)*
The Arch-Flo CT Midline is indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. This catheter may be inserted via basilic, cephalic, or median cubital vein.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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

K171483

1. **Submitter Information:**

Submitter:	Medical Components Inc. (dba Medcomp®) 1499 Delp Drive Harleysville, PA 19438 Tel: (215) 256-4201 Fax: (215) 256-9191
Registration Number:	2518902
Contact:	Courtney Nix Cnix@Medcompnet.com Regulatory Affairs Manager, North America and EU
Date Prepared:	05/18/2017

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

Trade Name:	Arch-Flo™ CT Midline
Common/Usual Name:	Midline Catheter
Product Code:	PND
Regulation Description:	Intravascular Catheter
C.F.R. Section:	880.5200
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

3. **Predicate Device Information:**

510(k) Number:	K141151
510(k) Holder:	Medical Components Inc. (dba Medcomp®)
Trade Name:	CT Midline
Common/Usual Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days

Product Code:	LJS
Regulation Description:	Percutaneous implanted, Long-Term intravascular catheter
C.F.R Section:	880.5970
Class:	II
Regulation Medical Specialty and Review Panel:	General Hospital

Note: Midline Intravascular catheters have their own product code now- PND. This is the reason the predicate has a different product code and regulation number.

4. Device Description:

The Arch-Flo™ CT Midline is available in a 4F Single Lumen configuration. The catheter lumen terminates through an extension to a female luer-lock connector. The extension has an in-line clamp to control fluid flow and is marked POWER INJECTABLE MIDLINE along with the lumen gauge size. The transition between lumen and extension is housed within a molded hub. The hub is marked MIDLINE to identify that the catheter is not centrally placed. The tip of the lumen is notched to increase the exposed area of the lumen. The outside diameter of the lumen increases gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen is marked with depth marks every centimeter.

5. Indications for Use:

The Arch-Flo™ CT Midline is indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media.

This catheter may be inserted via the basilica, cephalic, or median cubital vein.

6. Comparison to Predicate Devices:

Arch-Flo™ CT Midline is substantially equivalent to the predicate device, CT Midline (K141151), in terms of indications of use, intended use, anatomical location, design, performance, labeling, and method of sterilization.

The difference or changes between the Arch-Flo™ CT Midline and the predicate, CT Midline (K141151), is the radius arched tip, catheter length, luer and hub colorant. The differences in technological characteristics do not raise different questions of safety and effectiveness.
The yellow luer and hub, along with the printing, are intended to distinguish that the catheter is a Midline.

Table 5.1: 510(K) Summary: Design Comparison Matrix

Device	**Proposed Device:** Arch-Flo™ CT Midline (Proposed)	**Predicate Device:** CT Midline (K141151)
Indications for Use	The Arch-Flo™ CT Midline Catheter is indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. This catheter may be inserted via the basilic, cephalic, or median cubital vein	The CT Midlines are indicated for Short-Term peripheral access to the peripheral venous system for selected intravenous therapies, blood sampling, and power injection of contrast media. This catheter may be inserted via the basilic, cephalic, or median cubital vein.
Design	**Catheter:** OD 4F **Extension:** I.D .070 ± .002 O.D .106 ± .002	**Catheter:** OD 4F OD 5F **Extension:** I.D .070 ± .002 O.D .106 ± .002
Catheter Length	10 cm	20 cm
Lumen Marking	Number every 5cm and depth mark every cm.	Number every 5cm and depth mark every cm
Tip Design	Radius Arch Tip	Box
Dimensions or Lengths	4F X 10 cm	4F X 20 cm 5F X 20 cm
Materials	**Hub (Yellow)**: Pellethane **Lumen (White):** Tecothane w/ 20% BaSO4 **Extensions (Clear) and Luer (Yellow) Sub-Asm:** Isoplast **Tubing Clamp (Purple):** Acetal	**Hub (White):** Pellethane **Lumen (White) :** Tecothane w/ 30% BaSO4 **Extension (Clear) and Luer (Natural) Sub Asm:** Isoplast **Double:** **Extension (Clear) and Luer (Red) Sub-ASM:** Isoplast **Tubing Clamp (Purple):** Acetal

	Small ID Ring: ABS	**Small ID Ring:** ABS
French Size	4F	4F and 5F
Lumen Configuration	Single	Single and Double
Sterilization Method	ETO	ETO
Performance	**Max Power Injection Flow:** 5cc/sec **Priming Volume:** 0.36cc **Gravity Flow:** 56 ml/min	**Max Power Injection Flow:** 5cc/sec **Priming Volume:** 0.41cc **Gravity Flow:** 31.5 ml/min

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

The results of performance testing, in conjunction with the substantial equivalence claims, effectively demonstrate the proposed device, Arch-Flo™ CT Midline, is equivalent to the predicate device, CT Midline (K141151). The performance testing was performed in accordance with the following standards:

Standard	Standard Title	Revision/Date	Performance Testing
ISO 10555-1	Intravascular Catheter -- Sterile and Single – Use Intravascular Catheters – Part 1: General Requirements	Second edition 2013-06-15	Air Leakage, Liquid Leakage, Force at Break, Elongation, Gravity Flow, Chemical Exposure, Maximum Burst Pressure, Power Injection Flow Rate, Cyclic Flexure
11607-1 and 11607-2	Packaging for terminally sterilized medical devices - Part 1: requirements for materials, sterile barrier systems and packaging systems Part 2: validation requirements for forming, sealing and assembly processes	First edition 2006-04-15	Transit Testing (ISTA) Post Aging (ASTM F 1980)
ISO 10555-3	Intravascular Catheters – Sterile And Single-Use Catheters – Part 3: Central Venous Catheters	Second Edition 2013-06-15	Air Leakage, Liquid Leakage, Gravity Flow

Sterilization:

Sterilization Validation: ANSI/AAMI/ISO 11135-1:2014; AAMI TIR 2 8:2009/(R) 2013

Sterility Assurance Level: SAL is 10^{-6}.

Description of Validation Method:
Sterilization Method: The product is sterilized by 100% Ethylene Oxide (EO) Gas[1] in a fixed chamber.

ETO Residual Level: In accordance with AAMI/ANSI/ISO 10993-7:2008, Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide Sterilization Residuals, the maximum allowable limits for EO and ECH was less than or equal to the sterilant residual limits per ISO 10993-7 for a prolonged exposure device (>24 h <30 days): EO ≤4 mg first 24 hours and ECH ≤9 mg first 24 hours.

Pyrogen Test Method (LAL): Tested in accordance with ANSI/AAMI ST72:2011 Bacterial Endotoxin–Test methods, routine monitoring, and alternatives to testing the product is Non-pyrogenic.

Endotoxin: Tested in accordance with ANSI/AAMI ST72:2011 Bacterial Endotoxin–Test methods, routine monitoring, and alternatives to testing the maximum level is 20 EU/device.

8. Biocompatibility:

Biocompatibility was performed for the Arch-Flo™ CT Midline per ISO 10993-1 for a blood implant device with prolonged exposure (i.e. > 24 hours < 30 days). The biological endpoints and reference standard are as follows:

- Sensitization/Irritation:
  - *ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for Irritation and Skin Sensitization*
- Acute Systemic Toxicity:
  - *ISO 10993-11: 2006 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*
- Pyrogenicity (Materials Mediated) :
  - *ISO 10993 – 11 2006 Biological Evaluation of Medical Devices Part 11: Tests for Systemic Toxicity*
- Hemocompatibility:
  - *ISO 10993-4: 2002 Amended 2006 Biological Evaluation of Medical Devices – Part 4: Selection for tests for interactions with blood*
  - ASTM F 756-08, *Standard Practice for Assessment of Hemolytic Properties of Materials, 2008*

- ASTM F 619-03, *Standard Practice for Extraction of Medical Plastics, 2008*.
- Genotoxicity:
  - *ISO 10993-3 : 2003 Biological Evaluation of Medical Devices – Part 3 : Tests for genotoxicity, carcinogenicity and reproductive toxicity*
- Cytotoxicity:
  - *ISO 10993 -5: 2009 Biological Evaluation of Medical Devices – Part 10: Tests for in Vitro Cytotoxicity*
- Implantation:
  - *ISO 10993-6 : 2016 Biological Evaluation of Medical Devices – Part 6: Tests for local effects after implantation*

9. Summary of Substantial Equivalence:

In conclusion, the proposed device, Arch-Flo™ CT Midline, is considered substantially equivalent to the predicate device, CT Midline (K141151) as demonstrated through non-clinical testing performed.