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K141151

JUL 0 8 2014

Section 5 **510(k) SUMMARY** **Traditional 510K**

Submitter Information:

Submitter: MEDCOMP®
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Contact: Timothy Holwick, Regulatory Principal
Date Prepared: July 1, 2014

Device Name: CT Midline
Common Name: Percutaneous, Implanted, Intravascular Catheter
Classification Name: Long Term Intravascular Catheter
C.F.R. Section: 880.5970
Classification Panel: General Hospital
Class: II, LJS

Predicate Devices:
Primary:
K121094, Midline, concurrence date June 6, 2012, Class II, 21 CFR 880.5970
K091953, Pro-PICC CT, concurrence date September 16, 2009, Class II, 21 CFR 880.5970

Device Description:

The CT Midline Catheter is designed for peripheral vein catheterization and power injection of contrast media. The lumen is an open-ended design comprised of a soft radiopaque polyurethane material with barium sulfate for radiopacity. The lumen is connected to the extensions via a soft pliable hub with suture wing for secure placement. Clamps are provided on the extension tubes to prevent air/fluid contamination. Female luer connectors provide the connection for intravenous administration.

The CT Midline Catheter is available in a 4Fx20cm single-lumen, or 5Fx20cm double-lumen configuration. The outside diameter of the lumen has a reverse taper increasing gradually near the hub to aid in kink resistance and to provide a mechanical obstruction to bleeding from the venotomy. The lumen has depth marks every centimeter and numerical marks every fifth centimeter. The CT Midline is packaged sterile with the necessary accessories to facilitate insertion.

Intended Used:

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.

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Indications for Use:

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. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

Comparison to Predicate Devices:

The CT Midline is substantially equivalent to the predicate devices in terms of intended use, materials, anatomical location, basic design, performance, labeling, manufacturing process and method of sterilization.

Attribute	CT Midline (Proposed)	Midline (Predicate) K121094	Pro-PICC CT (Predicate) K091953
INDICATIONS FOR USE:	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. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.	The Midline catheters are indicated for short or long term peripheral access to the peripheral venous system for selected intravenous therapies and blood sampling. (see Contraindications) For blood therapy it is recommended that a 4French or larger catheter is used.	The PRO-PICC® CT catheter is indicated for short term or long term peripheral access to the central venous system for intravenous therapy and power injection of contrast media and allows for central venous pressure monitoring when a 20gauge or larger lumen is used. For blood sampling, infusion or therapies use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.
WHERE USED:	Hospital	Hospital	Hospital
STERILITY:	100% Ethylene Oxide	100% Ethylene Oxide	100% Ethylene Oxide
BIOCOMPATIBILITY:	Materials are identical to legally marketed	Legally Marketed 510(k) K121094	Legally Marketed 510(k) K091953

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Attribute	CT Midline (Proposed)	Midline (Predicate) K121094	Pro-PICC CT (Predicate) K091953
	K121094 with the exception of the Acetal clamp which was cleared in legally marketed K091953. Biocompatibility summaries located in Section 15 page 1.		
MATERIALS AND ADDITIVES:	**LUMEN**: Thermedics Tecothane TT2095A (30% Barium Sulfate) **PRINTING**: Markem, Black **HUB and SUTURE WING**: Dow Pellethane 2363-80A **LUERS**: Isoplast 2510. Natural White additives: Titanium Dioxide. EXTENSIONS: Dow Pellethane 2363-80A **CLAMPS**: Halkey Roberts Acetal Copolymer- Purple – single lumen Purple– double lumen **I.D. RING**: ABS Lustran 348 Drawings in Section 11.	**LUMEN**: Thermedics Tecothane TT2095A (30% Barium Sulfate) **PRINTING**: Markem, Black **HUB and SUTURE WING**: Dow Pellethane 2363-80A **LUERS**: Isoplast 2510. Natural White additives: Titanium Dioxide. EXTENSIONS: Dow Pellethane 2363-80A **CLAMPS**: Halkey Roberts Acetal Copolymer- Natural – single lumen Natural– double lumen **I.D. RING**: ABS Lustran 348 Drawings in Section 11.	**CLAMPS:** Halkey Roberts Acetal, Purple
Design Specifications	**LUMEN and TAPER LENGTH AVG.:** Single lumen 4F, -	**LUMEN and TAPER LENGTH AVG.:** Single lumen 4F, -	N/A

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Attribute	CT Midline (Proposed)	Midline (Predicate) K121094	Pro-PICC CT (Predicate) K091953
	short taper 2.756 inch (7cm) (Midline) Double 5F – long taper 3.44 to 5.44 inch. **LUMEN I.D./O.D. AVG.**: Proximal to taper (applies to both short and long taper) 4F Single: I.D. .045 inch (1.14mm) O.D. .082 inch (2.08mm) 5F Double*: I.D. .039 inch (.99mm) O.D. .092 inch (2.24mm) * Equivalent diameter of each lumen based on D-lumen cross-section area. **TIP LUMEN I.D./O.D. AVG.**: 4F Single: I.D. .032 inch (.81mm) O.D. .052 inch (1.32mm) 5F Double*: I.D. .031 inch (.79mm) O.D. .068 inch (1.73mm) * Equivalent diameter of each lumen based on D-lumen cross-section area. **LUMEN LENGTH**: 20cm (midline). Open ended design. **DEPTH**	short taper 2.756 inch (7cm) (Midline) Double 5F – long taper 3.44 to 5.44 inch. **LUMEN I.D./O.D. AVG.**: Proximal to taper (applies to both short and long taper) 4F Single: I.D. .045 inch (1.14mm) O.D. .082 inch 2.08mm) 5F Double*: I.D. .039 inch (.99mm) O.D. .092 inch (2.24mm) * Equivalent diameter of each lumen based on D-lumen cross-section area. **TIP LUMEN I.D./O.D. AVG.**: 4F Single: I.D. ..032 inch (.81mm) O.D. .052 inch (1.32mm) 5F Double*: I.D. .031 inch (.79mm) O.D. .068 inch (1.73mm) * Equivalent diameter of each lumen based on D-lumen cross-section area. **LUMEN LENGTH**: 20cm (midline). Open ended design. **DEPTH**	

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Attribute	CT Midline (Proposed)	Midline (Predicate) K121094	Pro-PICC CT (Predicate) K091953
	MARKING: Number every 5cm and depth mark every cm. **HUB**: With suture wing, all models. Contains French size on hub. **LUER**: Easy Grip™ design. **EXTENSION AVG.**: Clear with clamp. 4F Single – 19 gauge 5F Double – 18 gauge **ALL SINGLE, AND DOUBLE EXTENSIONS**: I.D.: .070 inches O.D.: .106 inches **I.D. RING WITHIN CLAMP**: On CT Midline contains product name and Max rate of 7cc/sec. Drawings in Section 11.	**MARKING**: Number every 5cm and depth mark every cm. **HUB**: With suture wing, all models. Contains French size on hub. **LUER**: Easy Grip™ design. **EXTENSION AVG.**: Clear with clamp. 4F Single – 19 gauge 5F Double – 18 gauge **ALL SINGLE, AND DOUBLE EXTENSIONS**: I.D.: .070 inches O.D.: .106 inches **I.D. RING WITHIN CLAMP**: On Midline contains extension gauge and French size with lumen length. Drawings in Section 12.	
MECHANICAL/ PERFORMANCE TESTING:	AIR LEAKAGE: 4F All versions passed in accordance with ISO 10555-1, Annex D. Reference testing summaries and protocols in Section 18. 5F All versions passed in accordance with ISO 10555-1, Annex D. Reference testing summaries and protocols in Section 18. LIQUID LEAKAGE:		

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Attribute	CT Midline (Proposed)	Midline (Predicate) K121094	Pro-PICC CT (Predicate) K091953
	All versions passed in accordance with ISO 10555-1, Annex C. Reference testing summaries and protocols in Section 18.		
Power Injection Capability Testing	POWER INJECTION FLOW RATE: 4F: V-9131: **Power Injection Flow Rate / Injection Pressure** (Avg.) Flow Rate (cc/sec)- 4.9 Machine Pressure (psi)- 213 HYDAC Pressure (psi)- 168 5F: V-9077: **Power Injection Flow Rate / Injection Pressure** (Avg.) Flow Rate (cc/sec)- 6.9 Catheter Pressure (psi)- 244 HYDAC Pressure (psi)- 181 MAX STATIC BURST: 4F: V-9043: The average maximum burst pressure was 302±5psi. The range of burst pressures was 292-312 psi. 5F: V-9073: The average maximum burst pressure was 249±8psi. The range of burst pressures was 241-262 psi.		POWER INJECTION FLOW RATE: 4F: 4Fx50cm Single **Power Injection Flow Rate / Injection Pressure** (Avg.) Flow Rate (cc/sec)- 3.9 Machine Pressure (psi)- 183 5F: 5Fx55cm Double **Power Injection Flow Rate / Injection Pressure** (Avg.) Flow Rate (cc/sec)- 4.9 Machine Pressure (psi)- 212 MAX STATIC BURST: 4F: The average maximum burst pressure was 288±4psi. The range of burst pressures was 279-293 psi. All samples burst along the lumen. 5F: The average maximum burst pressure was 269±4psi. The range of burst pressures was 262-278 psi. All samples failed by rupture of the lumen.

Comparison to Predicate Devices (cont.):

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The proposed device is substantially equivalent to the predicate devices because the data demonstrates the proposed device matches the power injection indication and performance of the predicate K091953 while being otherwise identical to the K121094 predicate device.

Performance Standards:

Performance standards have not been established by the FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Nonclinical Performance Tests:

The following tests were performed to establish the device's equivalence to the relevant predicate device:

- Power Injection Flow Rate
- Max Static Burst

These tests highlight the relevant difference between the proposed device and predicate K121094 by testing for the safety and effectiveness of the proposed device with regard to the expanded indication for use of power injection. As the predicate K121094 was not indicated for power injection, the K091953 performance data is discussed in this submission to establish that the proposed device is substantially equivalent in terms of power injection performance.

Biocompatibility:

Results for all biocompatibility testing demonstrate the materials used meet the requirements of ISO 10993.

Technological Characteristics:

The principles of operation are the same as the predicate devices, with the exception that the proposed device is indicated for power injection of contrast media. Fundamentally, the proposed device is physically identical to the predicate K121094 aside from the clamp, which is now colored purple to indicate power injection. The purpose of this submission is to establish that the proposed device can be properly indicated for power injection as supported by the provided data. There are no new questions raised regarding the safety or effectiveness of the device.

Summary of Substantial Equivalence:

The proposed device meets the performance criteria of design verification as specified by ISO standards, guidance documents and test protocols. The proposed device has the same intended use, operation and function as the predicates. There are no differences that raise new issues of safety and effectiveness. The proposed device is substantially equivalent to the legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 8, 2014

Medical Components, Inc.
Timothy Holwick
International Principal Regulatory Associate
1499 Delp Drive
Harleysville, PA 19438

Re: K141151
Trade/Device Name: CT Midline
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, implanted, long-term intravascular catheter
Regulatory Class: II
Product Code: LJS
Dated: May 5, 2014
Received: May 6, 2014

Dear Mr. Holwick:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Erin I. Keith, M.S.
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)*
K141151

Device Name

Medcomp CT Midline

Indications for Use *(Describe)*

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. The maximum recommended infusion rate varies by catheter French size and is printed on the catheter.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Digitally signed by Richard C. Chapman -S
Date: 2014.07.08 11:11:27 -04'00'

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