November 21, 2018

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

Re: K180546
Trade/Device Name: Jet Power Injectable PICC
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: LJS
Dated: October 22, 2018
Received: October 23, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Geeta K.
Pamidimukkala -S

for 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180546

Device Name
Jet Power Injectable PICC

Indications for Use *(Describe)*
The Jet Power Injectable PICC 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. For blood sampling, infusion, or therapies, use a 4F or larger catheter.

The maximum recommended infusion rate varies by catheter. The maximum recommended infusion rate for the 3F Jet Power Injectable PICC is 1cc/sec and 5.0cc/sec for the 4F and 5F Jet Power Injectable PICC.

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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A. Submitter Information

Submitter Name:	Jet Medical Inc
Address:	97 Main Street Schwenksville, PA, 19473 USA
Registration Number:	3007345394
Contact Person:	Courtney Nix Cnix@medcompnet.com Medical Components Inc (dba Medcomp®) Regulatory Affairs Manager, North America and EU (Est. Registration Number: 2518902)
Date of Preparation:	19NOV2018

B. Subject Device

Trade Name:	Jet Power Injectable PICC
Common Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Product Code:	LJS
21 CFR Regulation:	880.5970
Class:	II
Classification Panel:	General Hospital

C. Predicate Device

Predicate Trade Name:	PRO-PICC® CT
510(k) Number:	K091953
510(k) Holder:	Medical Components Inc.
Common Name:	Catheter, Intravascular, Therapeutic, Long-Term Greater Than 30 Days
Regulation Name:	Percutaneous, Implanted, Long-Term Intravascular Catheter
Product Code:	LJS
21 CFR Regulation:	880.5970
Class:	II
Classification Panel:	General Hospital

D. Device Description:

A family of trimmable peripherally inserted central catheters made from specially formulated biocompatible medical grade materials. Catheters are packaged in a tray

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with accessories necessary for a percutaneous microintroducer introduction (Modified Seldinger or Seldinger Technique).

E. Indications For Use

The Jet Power Injectable PICC 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. For blood sampling, infusion, or therapies, use a 4F or larger catheter.

The maximum recommended infusion rate varies by catheter. The maximum recommended infusion rate for the 3F Jet Power Injectable PICC is 1cc/sec and 5.0cc/sec for the 4F and 5F Jet Power Injectable PICC.

F. Intended Use

The Jet Power Injectable PICC 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. For blood sampling, infusion, or therapies, use a 4F or larger catheter.

G. Comparison to Predicate Device(s):

Table 6.1: 510(k) Summary Design Comparison Matrix

Attribute	Jet Power Injectable PICC (Proposed Device)	Predicate Device Pro-PICC® CT (K091953)	Status
Indications for Use	The Jet Power Injectable PICC 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. For blood sampling, infusion, or therapies, use a 4F or larger catheter. The maximum recommended infusion rate varies by catheter. The maximum	The Pro-PICC® CT is indicated for short 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 20 gauge 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.	Substantially equivalent; both devices are intended for short or long term peripheral access to the central venous system for infusion, blood sampling, and injection of contrast media.

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	recommended infusion rate for the 3F Jet Power Injectable PICC is 1cc/sec and 5.0cc/sec for the 4F and 5F Jet Power Injectable PICC		
Catheter OD	3F Single Lumen 4F Single Lumen 5F Double Lumen	4F Single Lumen 5F Single and Double Lumen 6F Double Lumen	Substantially Equivalent
Lengths	**3F Single Lumen, 4F Single Lumen, and 5F Double Lumen:** 55CM	**4F Single Lumen:** 50CM **5F Single Lumen** 60 CM **5F and 6F Double Lumen** 55CM	Substantially Equivalent
Duration of Use	**Short Term:** Greater than 24 hours but less than or equal to 30 days) **Long Term:** Greater than 30 days	**Short Term:** Greater than 24 hours but less than or equal 30 days **Long Term:** Greater than 30 days	Identical
Means of Insertion	Modified Seldinger or Seldinger Technique	Modified Seldinger or Seldinger Technique	Identical
Vascular Access Placement	Basilic vein Median Cubital Vein Cephalic Vein	Basilic vein Median Cubital Vein Cephalic Vein	Identical
Preferred Location	Basilic vein	Basilic Vein	Identical
Final anatomical location of Tip	Superior Vena Cava	Superior Vena Cava	Identical
Patient Population	Adults	Adults	Identical
Material Colors	**3F and 4F Single Lumen** **Tubing Clamp:** Purple **Extension:** Clear **Luer**: Red	**4F and 5F Single Lumen** **Luer:** Purple **Tubing Clamp:** Purple **Extension:** Translucent Purple	Substantially Equivalent; biocompatibility testing

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	Single Lumen **Tubing W/ Taper:** White **Hub:** White **5F Double Lumen** **Tubing Clamp:** Purple **Extension:** Clear **Luer:** Natural **Luer:** Red **Double Lumen** **Tubing W/ Taper:** White **Hub:** White	**Hub** Purple **Lumen** Light Purple **5F and 6F Double Lumen** **Tubing Clamp:** Purple **Luer:** White **Luer:** Purple **Extension:** Translucent Purple **Hub:** Purple **Lumen** Light purple	
Depth Markings	Depth Markings are marked every 1cm. Numerical markings are placed every 5cm	Depth markings are marked every 1cm. Numerical markings are placed every 5cm.	Identical
Catheter Configuration	Single Lumen Double Lumen	Single Lumen Double Lumen	Identical
Sterility	EO	EO	Identical

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

Table 6.2: Performance Standards

Bench Testing	Applicable Performance Standard	Standard Title	Revision/Date
Liquid Leakage	**EN ISO 10555-1**	**Intravascular Catheter – Sterile and Single – Use Intravascular Catheters – Part 1 General Requirements**	**2009**
Air Leakage			
Force at Break			
Gravity Flow			
Chemical Exposure			
Max Static Burst Power Injection			
Elongation			
Accelerated Aging	**ASTM F 1980**	**Standard Guide for Accelerated Aging of Sterile Barrier System for Medical Devices**	**2016**

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Suture Wing Integrity	**Passed Per Internal Requirements**
Pump Flow Rate	
Priming Volume	
Catheter Collapse Test	
Catheter Stiffness	
Interaction Testing	
Simulated Use	
Tip Displacement During Power Injection	
Power Injection Flow Rate	
Dynamic Failure	
Power Injection Simulation Testing	
Cyclic Flexure / Kink Test	

All testing was conducted on dry catheters.

I. Biocompatibility:

Biocompatibility was performed for the 5F Jet Power Injectable PICC **per** ISO 10993-1 for an externally communicating device with permanent contact with circulating blood (greater than 30 days of contact). Biocompatibility was performed on the final finished device. The biological end points include:

Cytotoxicity

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

Sensitization

- ISO 10993-10 *Biological Evaluation of Medical Devices – Part 10: Tests for irritation and Skin Sensitization*
- OECD 406 Guidelines for Testing of Chemical, Test No. 406, Skin Sensitization

Irritation

- 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*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <151>, Pyrogen Test

Subchronic Toxicity

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- ISO 10993-11 *Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity*
- OECD 407 *Guidelines for the Testing of Chemicals, Test No. 407, Repeated Dose 28-Day Oral Toxicity Study in Rodents*

Genotoxicity

- ISO 10993-3 *Biological Evaluation of Medical Devices – Part 3: Tests for Genotoxicity, Carcinogenicity, and Reproductive Toxicity*
- OECD 471 *Guidelines for Testing of Chemicals, Test No.471, Bacterial Reverse Mutation Test*
- OECD 490 *Guidelines for the Testing of Chemicals, Test No. 490, In Vitro Mammalian Cell Gene Mutation Test Using the Thymidine Kinase Gene.*

Implantation

- ISO 10993-6 *Biological Evaluation of Medical Devices – Part 6: Tests for Local Effects After Implantation*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <88>, Biological Reactivity Tests, In Vivo, Implantation Test, Table 6: Evaluation of Encapsulation in the Implantation Test

Hemocompatibility

- ISO 10993-4 *Biological Evaluation of Medical Devices – Part 4: Selection of Tests for Interactions with Blood*
- ASTM F756 *Standard Practice for Assessment of Hemolytic Properties of Materials*

Further Testing

- European Pharmacopoeia 9th edition, section 2.2.24, Absorption Spectrophotometry, Infrared (2017)
- ISO 10993-18 *Biological Evaluation of Medical Devices – Part 18: Chemical Characterization of Materials*
- United States Pharmacopeia 40, National Formulary 35 (USP), General Chapter <197>, Spectrophotometric Identification Tests, Infrared Absorption

J. Sterility

Sterilization Validation:	ANSI/AAMI/ISO 11135-1:2014, AAMI TIR 28:2009(R)2013
Sterility Assurance Level	SAL is 10^{-6}
Sterilization Method:	The product is sterilized by 100% Ethylene Oxide (EO) Gas 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 level is less than to 4 mg/device.

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Pyrogen Test Method: 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.

K. Shelf Life

Shelf life testing was conducted per ASTM 1980F: 2016 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical devices as well as on the Jet Power Injectable PICC device using performance standard EN ISO 10555-1.

L. Summary of Substantial Equivalence:

In conclusion, the proposed device, Jet Power Injectable PICC, is considered substantially equivalent to the predicate devices, Pro-PICC® CT (K091953) as demonstrated through non-clinical testing performed.

The proposed device, Jet Power Injectable PICC, does not present any additional risks to patients or different considerations regarding equivalence than those presented by the predicate, Pro-PICC® CT (K091953). The proposed device, Jet Power Injectable PICC, and the predicate device, Pro-PICC® CT (K091953) are equivalent in terms of indications for use, intended use, specifications, anatomical location, biocompatibility, performance and labelling.