K140129

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JUL 0 2 2014

Section 5 510(k) Summary

The following information is being submitted in accordance with the requirements of 21 CFR 807.92.

Company Name:	ICU Medical, Inc
Address:	4455 Atherton Drive Salt Lake City, UT 84123
Contact Person:	Kristin Casper Regulatory Affairs Specialist ICU Medical, Inc. Phone: (801)264-1313 Fax: (801)264 1755
Preparation Date:	January 15, 2013
Device (Trade Name):	PICCOx Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter
Common/Usual Name:	Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter
Classification Names:	21 CFR 870.1230. Fiberoptic Oximeter Catheter. Product Code: DQE
Predicate Device:	K061585 ICU Medical, Inc. Opticath Central Venous Oximetry Catheter (also known as TriOx $ScvO_2$ Central Venous Catheter) K113277 Teleflex ArrowADVANTAGE™ Pressure Injectable PICC
Device Description:	The Peripherally Inserted, Pressure Injectable Central Venous Oximetry Catheter (PICCOx) is a single or multi-lumen catheter capable of intravenous infusion including pressure infusion up to 300psig, central venous pressure monitoring, venous blood sampling, and allows for continuous measurement of central venous oxygen saturation ($ScvO_2$) in the superior vena cava. The device includes fiber optics in a dedicated lumen for light transmission and single or multiple fluid lumens. Constructed of barium sulfate filled polyurethane, these catheters are radiopaque enabling the use of fluoroscopy or X-ray, to guide insertion and verify position. The maximum recommended infusion rate for the pressure injectable lumen is 5 mL/sec. Distance markings on the catheters provide a visual indication of insertion depth. Every 5cm the insertion depth is printed with an actual number and in between the numbers are black dots which are printed every 1cm. The catheter is non-trimmable, and offered in usable lengths of 40cm, 45cm, 50cm, and 55cm. Individual lumen hubs are ISO standard female luers which are adaptable to NeedleFree Connectors, syringes or IV tubing compliant with the ISO standard. The fiber optic lumen which is terminated in a housing, can be plugged into a compatible Optical Module. PICCOx is intended to be used with a user defined convenience kit. These "kits" are cleared under 510(k) K052865. All kits are terminally sterilized. The contents of the kit are sterile, medical devices intended for single patient use only with fluid path and invasive surfaces non-pyrogenic (or as indicated on the labeling of internal component packaging.)
Intended Use:	The Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter (PICCOx), is indicated for access to the central venous system for

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continuous in vivo measurement of the oxyhemoglobin saturation of blood ($ScvO_2$), intravenous therapy, blood sampling, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the PICCOx may not exceed 300 psi.

Technology: The PICCOx Peripherally-Inserted, Pressure-Injectable, Central Venous Oximetry Catheter employs the same fundamental scientific technology as its predicate devices. Technological characteristics of the subject PICCOx Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter are equivalent to those of the predicate ICU Medical, Inc. Opticath Central Venous Oximetry Catheter with respect to the basic catheter design and functionality including continuous in vivo measurement of the oxyhemoglobin saturation of blood ($ScvO_2$), intravenous therapy, blood sampling, and central venous pressure monitoring. Technical characteristics based on the subject device's peripheral insertion and power injection capabilities are comparable to the predicate Teleflex ArrowADVANTAGE™ Pressure Injectable PICC. Differences do not raise any new questions regarding safety and effectiveness. Please see Table 1 for more information.

Table 1: Summary Comparison of Technological Characteristics Table

Feature	PICCOx	Opticath® Central Venous Oximetry Catheter	ArrowADVANTAGE™
510K NUMBER	TBD	K061585	K113277
GENERAL CHARACTERISTICS			
Product Code	DQE	Same	LJS
Sterility	Supplied within a sterile package with non-pyrogenic fluid path.	Same	Same
Sterilization Method	Catheter is gamma irradiated.	Same	EO (Arrow Pressure Injectable PICC Promotional Materials)
Materials of Composition			
Shaft	Yellow polyurethane compound	Same	Polyurethane (K113277)
Junction	Yellow polyurethane resin	Same	Not known
Fiber Optics	Black coated fibers	Same	N/A
Optical	Polyurethane	Same	N/A
Coupler	Black ABS	Same	N/A
Lead Tubing	Polyurethane	Same	Not known

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Feature	PICCOx	Opticath® Central Venous Oximetry Catheter	ArrowADVANTAGE™
Luer	PCTG	Same	Not known
Clamps	ABS	Same	Not known
Technology			
Operating Principles	Multilumen catheters are capable of continuous measurement of central venous oxygen saturation ($ScvO_2$) in the superior vena cava. The catheter includes fiber optics for light transmission, multiple lumens with access hubs and shutoff clamps. Catheters are radiopaque enabling the use of fluoroscopy or X-ray to guide insertion and verify position. The distal end of the catheter is constructed of polyurethane that is radiopaque providing greater deflection when coming into contact with vessels, minimizing trauma to the vessels during use.	Same	The Arrow® Pressure Injectable PICC is a peripherally inserted central venous catheter (PICC) manufactured with medical grade, flexible polyurethane. The Arrow® PICC has a non-tapered catheter body with either a blunt tip or a Blue FlexTip® that is softer than a cut tip with a contour design to enhance maneuverability. The Blue FlexTip® also provides visual confirmation of an intact catheter upon removal. The kit components assist the clinician in maintaining maximal sterile barrier precautions. (Arrow Pressure Injectable PICC Promotional Materials)
Principle of Operation	Reflection Spectrophotometry	Same	N/A
Pressure Injection	Pressure injection of contrast media may not exceed 300 psi	N/A	Same (K113277)
Number of Pressure Injection	Ten	N/A	Same (Arrow Pressure Injectable PICC Promotional Materials)
Pressure Injectable Lumen Flow	Maximum flow rate of 5 mL/sec.	N/A	Same (K113277)
Manufacturing Process	Trained personnel using documented and validated procedures within a Quality	Same	Not known

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Feature	PICCOx	Opticath® Central Venous Oximetry Catheter	ArrowADVANTAGE™
Wavelengths	Three Wavelengths	Same	N/A
Calibration	*In vitro* using included calibration block or	Same	N/A
Preferred Insertion	Seldinger Technique	Same	Same (Arrow Pressure Injectable PICC Promotional Materials)
Central Venous System Access	Peripheral Access	Not indicated for peripheral placement.	Same (K113277)
Optical Module	2 Optic Fiber Mechanical Coupler	Same	N/A
Size	5 Fr 40-55 cm Single and multilumen	8 Fr 20 cm Multilumen	4, 5, & 6 Fr 40-55 cm Single and multilumen (K113277)
Needlefree Connector	MicroClave	Same	Same (Arrow Pressure Injectable PICC Promotional Materials)
Packaging	Tray and Pouch	Same	Not known
Distinct Labeling	Pressure injection capabilities are marked on the extension line offering a clear	N/A	Same
Connection to External Equipment	-Connected to the monitoring computer by inserting the optical connector into the optical module when measuring central venous oxygen saturation. -Administration sets are connected to the PICCOx catheter when delivering I.V. therapy to the patient. -Syringes are connected when obtaining blood samples or delivering drugs. -A manometer or an electronic pressure transducer with any	Same EXCEPT for pressure injector equipment.	Same EXCEPT for connected to the monitoring computer and optical module when measuring central venous oxygen saturation.

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Feature	PICCOx	Opticath® Central Venous Oximetry Catheter	ArrowADVANTAGE™
Duration	Short-term	Same	Short-term or long-term
Single Use	Yes	Same	Same

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Determination of Substantial Equivalence:	The demonstration of substantial equivalence is based on a comparison of features to the predicate devices and an assessment of non-clinical performance data. Information is included with this 510(k) submission that supports this determination. The PICCOx, Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter has the same indications for use, principles of operation and technological characteristics making it substantially equivalent to the predicate devices. No new issues of safety and efficacy have been raised.
Non Clinical Performance Data Summary	No performance standards have been established under Section 514 of the Food, Drug and Cosmetic Act for these devices. The PICCOx, Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter has been tested in accordance with its performance specification which accommodates known functional requirements. The PICCOx has been tested and passed the required testing for biocompatibility for external communicating devices, circulating blood, with prolonged exposure of > 24 hours and < 30 days and the Clear MicroClave has been tested and passed the required testing for biocompatibility for external communicating devices, blood path, indirect, prolonged contact > 24 hours and < 30 days according to the requirements of ISO 10993-1, Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing. The successful results of the key tests involving dynamic response, fiber optics, flow rates, leakage, force at break, lead tubing, markings, priming volumes, radiopacity, needlefree connector compatibility, and catheter to introducer fitment demonstrate that the proposed PICCOx Peripherally Inserted Central Venous Oximetry Catheter has met the pre-determined acceptance criteria applicable to the safe use of the devices.
Conclusion:	Performance testing included within this 510(k) demonstrates that the Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter (PICCOx) is safe, effective and performs in an equivalent manner to the predicate devices and in accordance with its intended use.

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 2, 2014

Icu Medical, Inc.
Kristin Casper
Regulatory Affairs Specialist
4455 Atherton Drive
Salt Lake City, UT 84123

Re: K140129
Trade/Device Name: PICCOx peripherally inserted, pressure injectable, central venous oximetry catheter
Regulation Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II
Product Code: DQE
Dated: June 5, 2014
Received: June 6, 2014

Dear Ms. Casper,

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.

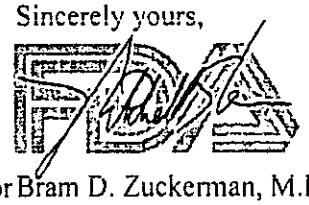
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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" (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.

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,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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)*
K140129

Device Name
PICCOx Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter

Indications for Use *(Describe)*
The Peripherally Inserted, Pressure Injectable, Central Venous Oximetry Catheter (PICCOx), is indicated for access to the central venous system for continuous in vivo measurement of the oxyhemoglobin saturation of blood (ScvO2), intravenous therapy, blood sampling, pressure injection of contrast media, and allows for central venous pressure monitoring. The maximum pressure of pressure injector equipment used with the PICCOx may not exceed 300 psi.

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)*

Date: 2014.07.02 14:45:15 -04'00'

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