



Food and Drug Administration
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January 20, 2016

PuraCath Medical, Inc.
John Ashley
Chief Technology Officer
660 4th Street, #104
San Francisco, CA 94107

Re: K151620
Trade/Device Name: Firefly™ Peritoneal Dialysis Connector Disinfecting System
Regulation Number: 21 CFR§ 876.5630
Regulation Name: Peritoneal dialysis system and accessories
Regulatory Class: II
Product Code: KDJ
Dated: December 15, 2015
Received: December 17, 2015

Dear John Ashley,

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,


Herbert P. Lerner -S

for 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

Indications for Use

510(k) Number (if known)
K151620

Device Name
Firefly™ Peritoneal Dialysis Connector Disinfecting System

Indications for Use (Describe)

The PuraCath™ Firefly™ Peritoneal Dialysis Connector Disinfecting System is intended for use by PD (peritoneal dialysis) patients as a method of controlling air and touch contamination while performing a solution exchange. The PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System is comprised of Firefly™ UV Purification Device, Firefly™ Transfer Catheter, Firefly™ Luer Cover, and Firefly™ 99% IPA bottle.

The effectiveness of the PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Streptococcus pneumoniae, Methicillin-resistant Staphylococcus aureus, and Candida albicans yielding ≥ 4 log reduction in micro-organisms.

The PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System may be used in the home or a healthcare facility.

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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510(K) SUMMARY

(21 CFR 807.92)

Applicant:

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San Francisco, CA 94107

Manufacturer:

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Contact Person:

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Chief Technology Officer
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Date Prepared:

December 14, 2015

Device Information:

Trade Name:	Firefly™ Peritoneal Dialysis Connector Disinfecting System
Classification:	Class II
Regulation Number:	21 CFR 876.5630
Product code:	KDJ

Product Description:

The PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System provides a way for patients to ensure the cleanliness of the fluid connections associated with ambulatory peritoneal dialysis. The system accomplishes cleaning with a combination of alcohol, flushing with sterile dialysate, and ultraviolet (UV) light. The System consists of the components shown below.



The Firefly UV Purification Device is a multi-year reusable device which helps to clean the connection between the Firefly Transfer Catheter and the dialysate Y-set (Y-set). The UV Purification Device is powered by off-the-shelf, replaceable AA batteries. The UV Purification Device directs ultraviolet (UV) light through the Transfer Catheter connector. UV Purification Device uses lights and an audible alert to indicate device status.

The Firefly Transfer Catheter is a sterile, 6 month use, disposable device providing communication between the indwelling patient catheter and the Y-set. A proprietary, UV transparent control valve on the end of the Transfer Catheter allows for draining and filling the peritoneum. The control valve is actuated manually, adjustable between fully open and fully closed. The Transfer Catheter also has a flush feature. The flush feature allows for flushing of air and potential contaminants from the Y-set prior to fluid exchange.

The Firefly Luer Cover is a 6 month use, disposable, UV transparent component designed to protect the Transfer Catheter connector between uses and to aid in keeping the control valve closed.

The Firefly IPA Dropper Bottle provides a convenient way to apply 99% IPA solution to the inside of the Y-set and Transfer Catheter connectors.

Indications for Use:

The PuraCath™ Firefly™ Peritoneal Dialysis Connector Disinfecting System is intended for use by PD (peritoneal dialysis) patients as a method of controlling air and touch contamination while performing a solution exchange.

The PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System is comprised of Firefly™ UV Purification Device, Firefly™ Transfer Catheter, Firefly™ Luer Cover, and Firefly™ 99% IPA bottle.

The effectiveness of the PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System was tested in vitro against *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Streptococcus pneumoniae*, Methicillin-resistant *Staphylococcus aureus*, and *Candida albicans* yielding ≥ 4 log reduction in micro-organisms.

The PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System may be used in the home or a healthcare facility.

Predicate Device(s):

- 1) K883239, Baxter healthcare, CAPD UV Germicidal Exchange Dev System



2) K142806, Catheter Connection, DualCap Disinfectant Cap

The Indications for Use statement for PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System is not identical to the predicate device's Indication for Use statement (K883239); however, the differences do not alter the intended use of the subject device nor do they affect the performance of the device relative to the predicate. Both the subject device and predicate device (K883239) have the same intended use.

Basic Technology Comparison with the Predicate Devices:

Disinfection of catheter connections is the general principle for both the subject and predicate devices. The subject device and the predicate device K883239 both use ultraviolet light as a means of disinfection. Both the subject device and the predicate device K883239 include substantially equivalent catheters and catheter luer caps as well as the ultraviolet light device. The subject device and the predicate device K142806 both use isopropyl alcohol as a means of disinfection. Both the subject device and the predicate device K142806 include substantially equivalent catheter luer caps.

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO 10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995.

The battery of tests included Cytotoxicity, Sensitization, and Irritation or Intracutaneous Reactivity.

Microbiological testing

In vitro antimicrobial efficacy studies were completed and show a ≥ 4 log reduction in each test micro-organism (Staphylococcus aureus, Staphylococcus epidermidis, Pseudomonas aeruginosa, Escherichia coli, Streptococcus pneumoniae, Methicillin-resistant Staphylococcus aureus, and Candida albicans).

Other performance tests



Additional testing was conducted to confirm that the PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System performs as intended. These include sterilization, electrical safety and electromagnetic interference, life cycle, light leak, transit, water ingress, and human factors – usability studies.

Performance Standards:

The following performance standards were adhered to and all applicable requirements were met.

- ISO 14971-1:2012
- AAMI/ANSI HE75:2009
- ISO 62366-1:2015
- ISO 15223-1:2012
- IEC 60601-1, 3rd edition
- ISO 10993-1:2009
- ISO 10993-7:2008
- ISO 594-2:1998

Conclusion:

Based on the data provided in this submission, it can be concluded that the PuraCath Firefly Peritoneal Dialysis Connector Disinfecting System is substantially equivalent to the predicate device in terms of intended use, design, materials, operation, function, and sterilization method. The performance bench tests completed in this submission demonstrate that the subject device is substantially equivalent to the predicate devices.