



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

November 19, 2014

Catheter Connections, Incorporated  
Dr. Donald D. Solomon, Ph.D.  
Sr. Vice President of Operations and Engineering  
Chief Technology Officer  
2455 East Parley's Way, Suite 150  
Salt Lake City, UT 84109

Re: K142399

Trade/Device Name: Dark Blue DualCap for Male Luers  
Regulation Number: Unclassified  
Regulation Name: Pad, Alcohol, Device Disinfectant  
Regulatory Class: Unclassified  
Product Code: LKB  
Dated: November 4, 2014  
Received: November 6, 2014

Dear Dr. Solomon:

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,

A handwritten signature in black ink that reads "Susan Runna DDS, MA". The signature is written in a cursive style. A faint, semi-transparent watermark of the letters "FDA" is visible behind the signature.

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

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

**Indications for Use**

510(k) Number (if known)

**K142399**

Device Name

Catheter Connections' Dark Blue DualCap for Male Luers

Indications for Use (Describe)

When left in place for five (5) minutes, the Dark Blue DualCap disinfects male luer connectors; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

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)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K142399

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

(21 CFR 807.92)

**for the Catheter Connections' Dark Blue DualCap® for Male Luers**

**SUBMITTER:**

**Catheter Connections, Inc.**

2455 East Parley's Way, Suite 150  
Salt Lake City, UT 84109

**CONTACT:**

Donald D. Solomon, Ph.D.

Telephone: (801) 209-1269

Fax: (888) 862-2693

Email: [dsolomon@cathconn.com](mailto:dsolomon@cathconn.com)

Date Prepared: August 7, 2014

**SUBMISSION DEVICE:**

Trade Name: Dark Blue DualCap® for Male Luers  
Regulation Number: Unclassified  
Regulation Classification Name: Pad, Alcohol, Device Disinfectant  
Regulatory Class: Unclassified  
Classification Product Code: LKB  
Classification Advisory Panel: General Hospital

**PREDICATE DEVICE:**

**DualCap® for Male Luers (K123967):**

(This predicate device has not been subject to a design-related recall)

(No reference devices were used in this submission)

Regulation Number: Unclassified  
Pad, Alcohol, Device  
Regulation Classification Name: Disinfectant  
Regulatory Class: Unclassified  
Classification Product Code: LKB  
Classification Advisory Panel: General Hospital

**DEVICE DESCRIPTION:**

The Dark Blue DualCap® is designed to fit securely on all ISO standard male luer connectors and provides effective disinfection of the male luer connector after five minutes of application. The cap contains 70% isopropyl alcohol. The product is intended for single-use and is provided sterile. This device is not made with natural rubber latex, is non-pyrogenic, preservative free and is not made with DEHP.

Additionally, Dark Blue DualCap® will be marketed for use as an accessory in procedure kits. When being used in procedural kits, the product will be shipped bulk sterile to the kitting manufacturer for incorporation into the procedure kits.

**INTENDED USE:**

The Dark Blue DualCap®, intended for use on male luer connectors, will disinfect and decontaminate male luer connectors and act as a barrier to contamination between uses.

The Dark Blue DualCap® will disinfect the connections within five (5) minutes after application and act as a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

**INDICATIONS FOR USE:**

When left in place for five (5) minutes the Dark Blue DualCap® disinfects male luer connectors; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

The difference in the Indications for Use for the submission device compared to the predicate device is a clarification that the Dark Blue DualCap® can be used on any male luer connector since male luers are dimensionally governed by an international standard (ISO) and are not device specific.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE:**

Disinfection of surfaces by exposure to 70% isopropyl alcohol (IPA) contained in a plastic cap while protecting the fluid pathway from disinfectant contamination is the general principle for both the submission and predicate devices. The submission and predicate devices are both based on the following technological elements:

- The devices are hermetically sealed and radiation sterilized
- They utilize an IPA reservoir
- They utilize an elastomeric tip to block the fluid pathway upon connection to a male luer
- There is an internal component which maintains the elastomeric tip noted above in contact with the orifice of the fluid pathway
- They have an ISO compliant female luer 6% taper dimensional feature to mate with male luer 6% taper feature
- They are mechanically secured via ISO compliant threads onto male luer connectors
- They disinfect and protect male luer connectors

There are no technological differences between the submission and the predicate device:

- The submission device is physically identical to the predicates device. They have the same technological characteristics:
  - Same design

- Same materials
- Same components
- Same method of manufacture
- Same plastic injection molds used to make the polypropylene Dark Blue caps
- Same method of operation
- Same sterilization method
- No change in the function/performance indication
- No change in patient population
- No change in clinical context

### **PERFORMANCE DATA**

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

#### **Biocompatibility testing**

The biocompatibility evaluation for the dark blue cap 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 submission device and predicate devices are identical. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation or Intracutaneous Reactivity
- Systemic Toxicity
- Hemocompatibility
- Pyrogen

#### **Microbiological testing**

Time Kill Studies were conducted for the evaluation of products for antimicrobial activity against selected organisms using an industry standard protocol for time-kill assays (ASTM E 2315-03, 2008). The product is challenged with the test organism(s) and then assayed at selected time points to determine antimicrobial efficacy on a wide range of microorganisms such as *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Streptococcus pyogenes*, antibiotic-resistant bacteria such as MRSA, VRE and yeasts such as *Candida albicans* and *Candida krusei*. The study has shown a  $\geq 4$  log reduction in all cases.

Additional *in vitro* antimicrobial efficacy studies were completed on the Dark Blue DualCap® for Male Luers under worst case conditions and show a  $\geq 4$  log reduction in each test organism (*Staphylococcus aureus*, *Staphylococcus epidermidis*, *Pseudomonas aeruginosa*, and *Escherichia coli*).

#### **Other performance tests**

Physical tests were performed to ensure that Dark Blue DualCap® for Male Luers was compatible with typical male luer devices such as those found on IV administration sets and

syringes. Applicable testing using ISO 594-1 and ISO 594-2 was completed. The Dark Blue DualCap® for Male Luers passed all tests.

Testing was also completed to demonstrate that the Dark Blue DualCap® for Male Luers did not allow disinfectant to enter into the fluid path of the male luers.

### **CONCLUSION**

The Submission Device is physically identical to the predicate device in terms of intended use, design, materials, operation, function, and sterilization method. All established acceptance criteria for performance testing for the predicate are identical to the Submission Device. This demonstrates that the Submission Device is safe and effective for its intended use, and based on FDA's 510(k) Decision-Making Flowchart is substantially equivalent to the Dark Blue cap of the Predicate Device (K123967).