Catheter Connections, Inc.
Donald D. Solomon
President and COO
615 Arapeen Drive, Suite 302a
Salt Lake City, Utah 84108

March 11, 2022

Re: K123967
Trade/Device Name: Catheter Connections' Dark Blue Dualcap For Male Luers
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Donald D. Solomon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 22, 2013 and the correction letter dated December 14, 2018. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation 880.5440.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Payal Patel, OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices, 240-402-6029, Payal.Patel@fda.hhs.gov.

Sincerely,

Payal Patel
Assistant Director for General Hospital Devices
DHT3C: Division of Drug Delivery and General Hospital Devices and Human Factors
OHT3: Office of GastroRenal, Ob-Gyn, General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

FDA U.S. FOOD & DRUG ADMINISTRATION

December 14, 2018

Catheter Connections, Inc.
Donald Solomon
President & Coo
2455 E Parleys Way - Suite 150
Salt Lake City, Utah 84109

Re: K123967
Trade/Device Name: Catheter Connections' Dark Blue Dualcap For Male Luers
Regulatory Class: Unclassified
Product Code: QBP
Dated: December 19, 2012
Received: December 26, 2012

Dear Donald Solomon:

This letter corrects our substantially equivalent letter of January 22, 2013.

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 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,

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

Indications For Use

510(k) Number (if known): K123967

Device Name: **Catheter Connections' Dark Blue DualCap™ for Male Luers**

Indications For Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Richard C. Chapman
Date: 2013.01.22 16:54:20 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K123967

K123967

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

JAN 2 2 2013

(21 CFR 807.92)
for Catheter Connections' Dark Blue DualCap™ for Male Luers

SUBMITTER:

Catheter Connections, Inc.
615 Arapeen Drive, Suite 302a
Salt Lake City, UT 84108

ESTABLISHMENT REGISTRATION NUMBER:
3009141010

CONTACT:

Donald D. Solomon, Ph.D.
President and COO
Telephone: (801) 209-1269
Fax: (888) 862-2693
Email: **dsolomon@cathconn.com**

DATE PREPARED:
December 18, 2012

MODIFIED DEVICE (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

SPONSOR'S CLEARED DEVICE – DualCap™ (K093229):

510(k) Holder of CLEARED DEVICE (K093229): Catheter Connections, Inc.

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

DEVICE DESCRIPTION:

The dark blue DualCap™ for male luers is designed to fit securely on IV administration male luer connections. 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, non-pyrogenic, preservative free and DEHP free.

INTENDED USE:

The dark blue DualCap™, intended for use on IV administration line male luer connectors, will disinfect and decontaminate the male luer connector and act as a barrier to contamination between IV administration line accesses.

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™ for male luer connectors disinfects the IV administration line male luer connectors; thereafter the caps provide a physical barrier to contamination up to ninety-six (96) hours under normal conditions if not removed.

TECHNOLOGICAL COMPARISON TO PREDICATE DEVICES:

1. **New device is compared to Marketed Device?** Yes. It is compared to legally marketed predicates (Sponsor's Cleared Device).
    a. Change (new packaging configuration) to the Modified Device
        i. Compared to the Marketed Device, the Modified Device of this submission contains a substantially equivalent hermetic foil/polymer seal also found in the Sponsor's Cleared Device.
        ii. Scientific methods used to assess the effects of the change in device packaging
            1. A comparison of the specifications was conducted to assess whether the hermetic foil/polymer material of the Modified Device was substantially equivalent to the hermetic foil/polymer material of the Sponsor's Cleared Device.
            2. A comparison of the specifications was conducted to assess whether the polymer sealing seal surface of the Modified Device was substantially equivalent to the polymer sealing surface of the Sponsor's Cleared Device.

2. **Does the new device have the same indication statements?** Yes.
   a. Change (new packaging configuration) to the Modified Device
      i. The dark blue disinfectant cap for both the Modified Device and the Sponsor's Cleared Device has the same Indications for use – to disinfect and protect male luer connectors.
   b. Scientific methods used to assess the effects of the change in device packaging
      i. A comparison of the label specifications was conducted to assess whether the indication statements of the Modified Device was identical to the indication statements of the Sponsor's Cleared Device. The indication statements were found to be substantially equivalent.
   c. Results that support substantial equivalence

	Specification Cleared Device	Specification Modified Device	Results
Indication for Use Statements	"...disinfect and protect male luer connectors..."	"...disinfect and protect male luer connectors..."	Identical

3. **Do the differences alter the intended therapeutic/diagnostic/etc. effect (i.e. deciding may consider impact on safety and effectiveness)?** No, the differences do not alter the intended use of the device.
   a. Change (new packaging configuration) to the Modified Device
      i. The Modified Device is used in the same way for the same intended use of disinfecting and protecting luer access valves. The Modified Device is used and applied to male luer connectors in exactly the same way the Sponsor's Cleared Device is used.
   b. Scientific methods used to assess the effects of the change in device packaging
      i. A comparison of the label specifications was conducted to assess whether the changes alter the intended therapeutic/diagnostic/etc. The change in packaging effect of the Modified Device does not alter the intended use compared to the intended therapeutic/diagnostic/etc. effect of the Sponsor's Cleared Device.

   c. Results that support substantial equivalence

	Specification Cleared Device	Specification Modified Device	Results
Intended Use	"...disinfect and decontaminate the male luer connector and act as a barrier to contamination between IV administration line accesses."	"...disinfect and decontaminate ... the male luer and act as a barrier to contamination between IV administration line accesses."	Dark Blue disinfecting cap has the same intended use in the Modified Device and the Sponsors Cleared Device

4. **Does the new device have the same technological characteristics, e.g. design, material, etc.?** Yes. The Modified Device is substantially equivalent in design, materials, sterilization method and method of operation. **The basic fundamental scientific technology of the device has not changed.**
    a. Change (new packaging configuration) to the Modified Device
        i. The technological characteristics of the Modified Device are equivalent to that of the Sponsor's Cleared Device. Both the Modified Device and the Sponsor's Cleared Device retains the hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
        ii. Scientific methods used to assess the effects of the change in device packaging
            1. A comparison of the requirements (design input) and verification characteristics of the Modified Device are equivalent to the technological characteristics of the Sponsor's Cleared Device.
            2. Results that support substantial equivalence show that a specification comparison between the Cleared Device and the Modified Device comparing design, materials, sterilization method, and method of operation were all substantially equivalent.

5. **Could the new characteristics affect safety or effectiveness?** No.
    a. Change (new packaging configuration) to the Modified Device
        i. The safety and effectiveness of the Modified Device are equivalent to that of the Sponsor's Cleared Device. Both the Modified Device and the Sponsor's Cleared Device have a hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
    b. Scientific methods used to assess the effects of the change in device packaging
        i. Risk Analysis was used to assess the impact of the modification
        ii. All tests were completed and showed substantial equivalence

6. **Do the new characteristics raise new types of safety and effectiveness questions?** No. There are no new types of safety and effectiveness questions.
    a. Change (new packaging configuration) to the Modified Device
        i. The safety and effectiveness of the Modified Device are equivalent to that of the Sponsor's Cleared Device. Both the Modified Device and the Sponsor's Cleared Device have a hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
    b. Scientific methods used to assess the effects of the change in device packaging
        i. Risk Analysis was used to assess the impact of the modification
    c. Risk Analysis Method identified the need to perform a standard Peel Test to assess the impact of the modification – results were substantially equivalent.

7. **Do accepted scientific methods exist for assessing effects of the new characteristics?** Yes.
   a. Change (new packaging configuration) to the Modified Device
      i. The effects of the new characteristics of the Modified Device can be assessed using accepted scientific methods. Both the Modified Device and the Sponsor's Cleared Device have a hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
   b. Scientific methods used to assess the effects of the change in device packaging
      i. Sterilization requirements of ISO 11137:2006, Sterilization of Health Care Products - Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
      ii. Biocompatibility requirements according to of ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

8. **Are performance data available to assess effects of new characteristics?** Yes. Verification testing was performed according to protocols based on the above-referenced guidance document recommendations and additional standards and protocols.
   a. Change (new packaging configuration) to the Modified Device
      i. The effects of the new characteristics of the Modified Device can be assessed using available performance data. Both the Modified Device and the Sponsor's Cleared Device have a hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
   b. Performance data used to assess the effects of the change in device packaging
      i. Standard Peel strength tests were used and showed substantial equivalence.

9. **Do performance data demonstrate equivalence?** Yes. Performance data gathered demonstrated that the Modified Device is substantially equivalent to the noted predicate (Sponsor's Cleared Device).
   a. Change (new packaging configuration) to the Modified Device
      i. The equivalence of the new characteristics of the Modified Device can be demonstrated using available performance data. Both the Modified Device and the Sponsor's Cleared Device have a hermetic foil/polymer seal. Both the Modified Device and the Sponsor's Cleared Device retain the identical structure and components to be used for the same indications in the same manner.
   b. Scientific methods used to assess the effects of the change in device packaging
      i. Standard Peel strength tests were used and showed substantial equivalence.

CONCLUSION

The Catheter Connections' Dark Blue DualCap® meets all established acceptance criteria for performance testing. This testing and comparison demonstrated that the Catheter Connections' Dark Blue DualCap® is safe and effective for its intended use, and based on FDA's decision tree is substantially equivalent to the above noted Sponsor's Cleared Device (DualCap™ - K093229).