

JAN 27 2012

K113842

**CATHETER CONNECTIONS, INC.**

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510(k) Premarket Notification Submission: **Catheter Connections' DualCap Solo™**

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

(21 CFR 807.92)

**for Catheter Connections' DualCap Solo™**

**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](mailto:dsolomon@cathconn.com)

**DATE PREPARED:**

September 30, 2011

**MODIFIED DEVICE (Submission Device):**

Trade Name: DualCap Solo™  
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

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**DEVICE DESCRIPTION:**

The DualCap Solo™ is designed to fit securely on luer access valves. 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:**

DualCap Solo™ is intended for use on luer access valves. DualCap Solo™ will disinfect and decontaminate the valve and act as a barrier to contamination between IV administration line accesses.

DualCap Solo™ 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 DualCap Solo™ disinfects needleless luer access valves; 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:**

**New device is compared to Marketed Device?** Yes. It is compared to legally marketed predicates (Sponsor's Cleared Device).

**Does the new device have the same indication statements?** Yes.

**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.

**Does the new device have the same technological characteristics, e.g. design, material, etc.?** Yes. The Catheter Connections' DualCap Solo™ is substantially in equivalent design, materials, packaging, sterilization method and method of operation. The basic fundamental scientific technology of the device has not changed.

**Could the new characteristics affect safety or effectiveness?** No.

**Do the new characteristics raise new types of safety and effectiveness questions?** No. There are no new types of safety and effectiveness questions.

**Do accepted scientific methods exist for assessing effects of the new characteristics?** Yes.

Sterilization requirements of ISO 11137: 2006, Sterilization of health care products – Radiation.

Biocompatibility requirements according to of ISO-10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing.

These and other standards were used to determine the appropriate methods for evaluating the device's performance.

**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.

**Do performance data demonstrate equivalence?** Yes. Performance data gathered demonstrated that the Catheter Connections' DualCap Solo™ is substantially equivalent to the noted predicate (Sponsor's Cleared Device – DualCap™).

#### **CONCLUSION**

The Catheter Connections' DualCap Solo™ will meet all established acceptance criteria for performance testing. This testing demonstrated that the Catheter Connections' DualCap Solo™ 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).



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Catheter Connections, Incorporated  
C/O Dr. Donald D. Solomon  
President and COO  
615 Arapeen Drive, Suite 302a  
Salt Lake City, Utah 84108

JAN 27 2012

Re: K113842  
Trade/Device Name: Catheter Connections' DualCap Solo™  
Regulation Number: Unclassified  
Regulation Name: Pad, Alcohol, Device Disinfectant  
Regulatory Class: Unclassified  
Product Code: LKB  
Dated: December 22, 2011  
Received: December 28, 2011

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.

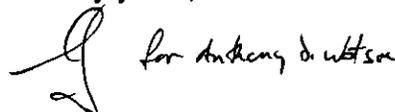
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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, appearing to read "Anthony D. Watson". The signature is stylized and written in cursive.

Anthony D. Watson, B.S., M.S., M.B.A.  
Director  
Division of Anesthesiology, General Hospital  
Infection Control and Dental Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Indications For Use

510(k) Number (if known): \_\_\_\_\_

Device Name: Catheter Connections' DualCap Solo™

Indications For Use:

When left in place for five (5) minutes, DualCap Solo™ disinfects needleless luer access valves; 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)

PHC [Signature] 1/25/12  
(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Anesthesiology, General Hospital  
Infection Control, Dental Devices

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