

K110826

5. **510(k) Summary**

General Company Information

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Contact: Don Canal
Consultant RAQA

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Date Prepared: May 19, 2011

General Device Description

The CuroTM Port Protector device is a single use, sterile device that contains 70% Isopropyl Alcohol and is intended to be used as a disinfectant for needleless luer activated valves.

Common Name: Pad, Alcohol
Trade Name: CuroTM Port Protector
Classification: Unclassified Device, product Code LKB

Predicate Devices

K080466 CuroTM Port Protector

Intended Use (Indications)

The Ivera Medical CuroTM Port Protector is a device containing 70% Isopropyl Alcohol. When left in place for 5 to 15 minutes the CuroTM Port Protector decontaminates the injection port; thereafter, the CuroTM Port Protector provides a physical barrier during the intended use.

Comparison with Predicate Device

The only change from the predicate device is that the Subject device is provided sterile with the revised labeling to add the sterile symbol. The materials of construction and technological characteristics are the same as the predicate device.

Substantial Equivalence Performance Testing

Ivera medical has provided non-clinical performance test data that demonstrates the pre-defined acceptance criteria for a disinfecting device has been met. This acceptance criteria is defined as a bacteria count reduction of ≥ 4 log reduction of 2 selected gram

positive bacteria and 2 selected gram negative bacteria for a period of time from 3 minutes up to 168 hours (7 days). The efficacy testing was completed using a total of 4 bacteria, 2-gram negative and 2 gram positive as recommended in Draft Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents DRAFT GUIDANCE. This guidance document is being distributed for comment purposes only. Document issued on: July 19, 2007. The bacteria tested and the test results are included in Table 1.

Table 1 - Efficacy Test Results

Organism	Acceptance Criteria (bacterial count reduction (Δ Log))	3 minute exposure (bacterial count reduction (Δ Log))	7 day (168 hours) exposure (bacterial count reduction (Δ Log))
Staphylococcus aureus	> 4.0	6.0	6.9
Staphylococcus epidermis	> 4.0	6.8	7.3
Escherichia coli	> 4.0	5.2	5.2
Pseudomonas aeruginosa	> 4.0	5.1	5.1

The data presented demonstrate the Subject Device is safe and effective, and the performance test results meet the requirements of its pre-defined acceptance criteria and intended uses.

The Ivera Curoc Port Protector is sterilized using a validated Gamma sterilization process which complies with ISO11137-1:2006/(R) Sterilization of health care products - Radiation - Part 2: Establishing the sterilization dose. Recognition number 14-225.

ISO11137-2:2006 Sterilization of health care products – Radiation – Part 1: requirements for development of validation and routine control of sterilization process for medical devices. Recognition number 14-297.

11137-3:2006/(R) 2010 10/04/2010 AAMI ANSI ISO 14-298 - Radiation - Part 3: Guidance on Dosimetric Aspects. Recognition number 14-298. FDA recognized standard ISO11137 Sterilization Standard.

Ivera Medical has completed testing to demonstrate the Curoc Port Protector materials of construction meet FDA recognized standard ISO10993 for biocompatibility.

Conclusions

The analysis arguments and test results demonstrate the Curoc™ device is substantially equivalent to the predicate devices.



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

Mr. Donald Canal
Consultant RAQA
Ivera Medical, Corporation
2731 Loker Avenue West
Carlsbad, California 92010

JUN 23 2011

Re: K110826
Trade/Device Name: The CuroTM Port Protector
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKB
Dated: May 26, 2011
Received: May 26, 2011

Dear Mr. Canal:

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,



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

Enclosure

4. Indications for Use Statement

Device Name: The CUROS™ Port Protector

Indications For Use:

The CuroS™ Port Protector is a device containing 70% Isopropyl alcohol. When left in place for 5 to 15 minutes the CuroS™ Port Protector decontaminates the injection port; thereafter the CuroS™ Port Protector provides a physical barrier during the intended use.

Prescription Use

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)


(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices
10(k) Number: K110826