

K111992
JAN 12, 2012

510(k) Summary

General Company Information

Name: Ivera Medical Corporation
Contact: Don Canal
Consultant RAQA

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Date Prepared: October 23, 2011

General Device Description

The CuroTMs 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: **CuroTMs Port Protector**
Classification: **Unclassified Device, product Code LKB**

Predicate Devices

K080466 CuroTMs Port Protector, Ivera Medical Corporation
K083508 SwabCap, Excelsior Medical Corporation

Intended Use (Indications)

The CuroTMs is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. CuroTMs will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of CuroTMs Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans and was found to have >4 log reduction. The CuroTMs Port Protector may be used in the home or healthcare facility.

Comparison with Predicate Device

There is no change to the device for this 510(k) notification, the only change is to the Intended Use (indications) to reflect the test data for disinfection which includes 3 minutes to 7 days (168 hours), as described below. The materials of construction and technological characteristics are equivalent to the predicate device.

Subject Device to Predicate Technological Comparison Table

Characteristic	Subject Device	Predicate Device	Predicate Device
Device name	Curos Port Protector	Curos Port Protector	SwabCap
Common Name	Alcohol, disinfecting pad	Alcohol, disinfecting pad	Alcohol, disinfecting pad
Manufacturer	Ivera Medical	Ivera Medical	Excelsior Medical Corporation
510(k) number	K110826	K110826	K083508
Regulation number, product code	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB	Unclassified, Preamendment device, product code: LKB
Indications for use	The Curos is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curos™ will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans	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.	SwabCap is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. SwabCap will disinfect the valve five (5) minutes after application and act as a physical barrier to contamination for up to ninety-six (96) hours under normal conditions if not removed.

Characteristic	Subject Device	Predicate Device	Predicate Device
	and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.		
Disinfectant – active ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	70% Isopropyl Alcohol
Length	0.40 inches	0.40 inches	0.50 inches
Diameter	0.54 inches	0.54 inches	0.60 inches
User Population	Home and hospital use	Home and hospital use	Home and hospital use
Colorants Used (type, amount, concentration)	Translucent green, molded plastic, 3% concentration	Translucent green, molded plastic, 3% concentration	Orange pigment, % concentration unknown
Provided Sterile	Yes	Yes	Yes
Single Use Device	Yes	Yes	Yes
Plastic Housing to remain in place	Yes	Yes	Yes

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, 2 selected gram negative bacteria, and two selected fungus/yeast micro-organisms 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 test results are summarized in Table 1.

Table 1 - Efficacy Test Results

Organism	Acceptance Criteria (bacterial count reduction (ΔLog))	3 minute exposure (bacterial count reduction (ΔLog))	7 day (168 hours) exposure (bacterial count reduction (ΔLog))
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
Candida Albicans	≥ 4.0	5.6	>4.8*
Candida Glabrata	≥ 4.0	5.4	>5.3*

* The entire population was killed, the reduction in bacteria count was limited to the population quantified by the positive controls used in the testing.

The Ivera Curos 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 Curos Port Protector materials of construction meet FDA recognized standard ISO10993 for biocompatibility.

Conclusion

The analysis arguments and test results demonstrate the Curos™ device is safe for its intended use and 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. Don Canal
Regulatory Affairs, Quality Manager
Ivera Medical, Incorporated
3525 Del Mar Heights Roads, Suite #430
San Diego, California 92130

FEB 10 2012

Re: K111992
Trade/Device Name: Curos™ Port Protector
Regulation Number: Unclassified
Regulation Name: None
Regulatory Class: II
Product Code: LKB
Dated: December 23, 2011
Received: December 23, 2011

Dear Mr. Canal:

This letter corrects our substantially equivalent letter of January 12, 2012.

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 (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.

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.

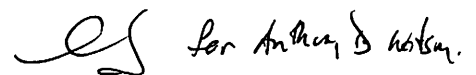
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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

The Curos is intended for use on swab-able luer access valves as a disinfecting cleaner prior to line access and to act as a physical barrier to contamination between line accesses. Curos™ will disinfect the valve three (3) minutes after application and act as a physical barrier to contamination for up to seven (7) days (168 hours) if not removed. The effectiveness of Curos Protectors were tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli and Pseudomonas aeruginosa, Candida glabrata, Candida albicans and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.

 for Anthony Dickson

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K111992

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)