Ivera Medical, Inc.
Don Canal
Regulatory Affairs, Quality Manager
3525 Del Mar Heights Road, Suite #430
San Diego, California 92130

March 11, 2022

Re: K111992
Trade/Device Name: Curos Port Protector
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Don Canal:

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 12, 2012 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

Ivera Medical, Inc.
Don Canal
RA/QA
2731 Loker Avenue West
Carlsbad, California 92010

Re: K111992
Trade/Device Name: Curos Port Protector
Regulatory Class: Unclassified
Product Code: QBP
Dated: July 13, 2011
Received: July 13, 2011

Dear Don 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 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

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 glibrata, Candida albicans and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.

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)

Richard C Chapman 1/9/12

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

510(k) Number: K111992

JAN 12 2012

510(k) Summary

General Company Information

Name:	Ivera Medical Corporation
Contact:	Don Canal Consultant RAQA
Address:	Ivera Medical Corporation 3525 Del Mar Heights Road Suite #430 San Diego, CA 92130
Telephone:	760-612-6090
Fax:	858-228-1770

Date Prepared: October 23, 2011

General Device Description

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

Predicate Devices

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

Intended Use (Indications)

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 glibrata, Candida albicans and was found to have >4 log reduction. The Curos 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 glibrata, Candida albicans	The Curos Port Protector is a device containing 70% Isopropyl Alcohol when left in place for 5 to15 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 $\geq$ 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.