Ivera Medical Corporation
Donald Canal
Vice President
3525 Del Mar Heights
Suite 430
San Diego, California 92130

March 11, 2022

Re: K080466
Trade/Device Name: Alcohol Pad
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Donald 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 October 21, 2008 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

122 Corporation
Donald Canal
Vice President
3525 Del Mar Heights
Suite 430
San Diego, California 92130

Re: K080466
Trade/Device Name: Alcohol Pad
Regulatory Class: Unclassified
Product Code: QBP
Dated: February 18, 2008
Received: February 21, 2008

Dear Donald Canal:

This letter corrects our substantially equivalent letter of October 21, 2008.

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

6. Indications for Use

K080466

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

510(k) Number: K080466

OCT 21 2008

1 of 2

2. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS per 21 CFR 807.92

General Company Information

Name: Ivera Medical Corporation
Contact: Don Canal
Vice President 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: September 29, 2008

General Device Description

The **Curos**™ Port Protector device is a single use, non-sterile device that contains 70% Isopropyl Alcohol and is intended to be used to decontaminate needleless luer activated valves.

Product Name: **Curos**™ Port Protector
Classification: Unclassified Device under product Code LKB

Predicate Devices

K833182 APLICARE Alcohol Prep Pad

Intended Use (Indications)

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.

K080466
2 of 2

Substantial Equivalence

Ivera medical has provided performance test data to satisfy the requirements of a decontaminating device by reducing the bacterial count two (2) selected gram positive bacteria and 2 selected gram negative bacteria. Ivera Medical also demonstrated equivalence to the predicate device with comparison test data.

The data presented demonstrate that the device is substantially equivalent to the Predicate Device and is suitable for its indicated use.

Conclusions

The test results and analysis of data demonstrate the **Curos**™ Port Protector is substantially equivalent to the predicate devices with comparison data.