Ivera Medical, Inc.
Don Canal
Vice President of Operations and Regulatory Affairs and Quality Assurance
3525 Del Mar Heights Road, Suite #430
San Diego, California 92130

March 11, 2022

Re: K121171
Trade/Device Name: Curos Tip
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 November 26, 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

U.S. FOOD & DRUG ADMINISTRATION

December 14, 2018

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

Re: K121171
Trade/Device Name: Curos Tip
Regulatory Class: Unclassified
Product Code: QBP
Dated: April 17, 2012
Received: April 17, 2012

Dear Don Canal:

This letter corrects our substantially equivalent letter of November 26, 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 Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips 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)**

Digitally signed by Richard C. Chapman
Date: 2012.11.21 11:26:03 -05'00'

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

**510(k) Number:**

K121171

## 5. 510(k) Summary

### General Company Information

NOV 26 2012


Name: Ivera Medical Corporation
Contact: Don Canal
Vice President of Operations and RAQA

Address: Ivera Medical Corporation
3525 Del Mar Heights Road
Suite #430
San Diego, CA 92130

Telephone: 972-955-7644
Fax: 858-228-1770


**Date Prepared: October 23, 2012**

### General Device Description

The Curos Tips™ are intended for use on IV administration lines Male luer as a disinfecting cleaner, which contains 70% IPA, prior to line connection and to act as a physical barrier to contamination between line accesses. The Curos Tips have a highly visible green color that may allow improved compliance by easy visual verification. The Curos Tips may be used in the home or healthcare facility.

Common Name: **Pad, Alcohol**
Trade Name: **Curos Tips™**
Classification: Unclassified Device, product Code LKB

### Predicate Devices

K111992 Curos Port Protector, Ivera Medical Corporation
K093229 Catheter Connections Dual Cap

### Intended Use (Indications)

The Curos Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips may be used in the home or healthcare facility.

## Comparison with Predicate Device

### Subject Device to Predicate Technological Comparison Table

| Characteristic | Subject Device K121171 | Curos Port Protector K111992 | Predicate Device K093229 |
|---|---|---|---|
| Device name | Curos Tips | Curos Port Protector | Dual Cap |
| Common Name | Alcohol, disinfecting pad | Alcohol, disinfecting pad | Alcohol, disinfecting pad |
| Manufacturer | Ivera Medical | Ivera Medical | Catheter Connections |
| 510(k) number | Subject Device | K111992 | K093992 |
| 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 Tips™ are intended for use as a disinfecting cleaner for male luer connectors. Curos Tips will disinfect the male luer (3) minutes after application and will cover the luer until removed. The effectiveness of the Curos Tips was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans. The Curos Tips may be used in the home or healthcare facility. | 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. | DualCap™ is intended for use on Luer access valves and the IV administration line male Luer connections. DualCap™ will disinfect and decontaminate the valve and male Luer and act as a barrier to contamination between IV administration line accesses.<br>DualCap™ 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. |
| Disinfectant – active ingredient | 70% Isopropyl Alcohol | 70% Isopropyl Alcohol | 70% Isopropyl Alcohol |
| Male Luer Connection | Yes | No | Yes |
| Female Luer Connection | No | Yes | Yes |
| Length | 0..76 inches | 0.40 inches | 1.82 inches |
| Diameter | 0.272 inches | 0.54 inches | 0.47 inches |
| User Population | Home and hospital use | Home and hospital use | Home and hospital use |

| Characteristic | Subject Device K121171 | Curos Port Protector K111992 | Predicate Device K093229 |
|---|---|---|---|
| Colorants Used (type, amount, concentration) | Translucent green, molded plastic, 3% concentration | Translucent green, molded plastic, 3% concentration | Blue, white Plastic, unknown material and pigment(s) |
| 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 3 minutes.

The efficacy testing was completed using a total of 6 bacteria. As recommended by the Draft Guidance for Industry and FDA Staff Premarket Notification [510(k)] Submissions for Medical Devices that Include Antimicrobial Agents DRAFT GUIDANCE Ivera completed the 2-gram negative and 2 gram positive bacteria. This guidance document is being distributed for comment purposes only. Document issued on: July 19, 2007. Ivera has also completed testing on 2 fungus/yeast micro-organisms Candida Albicans and Candida Glabrata. 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)) |
|---|---|---|
| **Staphylococcus aureus** | **≥4 Log** | **6.61** |
| **Staphylococcus epidermis** | **≥4 Log** | **6.48** |
| **Escherichia coli** | **≥4 Log** | **6.53** |
| **Pseudomonas aeruginosa** | **≥4 Log** | **6.49** |
| **Candida Albicans** | **≥4 Log** | **6.60** |
| **Candida Glabrata** | **≥4 Log** | **6.64** |

The Ivera Curos Tips are 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 materials of construction for the Subject Device meet FDA recognized standard ISO10993 for biocompatibility.

**Conclusion**

The analysis arguments and test results demonstrate the Curos Tips™ device is safe for its intended use and is substantially equivalent to the predicate devices.