3M Company
Dianne Gibbs
Regulatory Affairs Manager
2510 Conway Ave.
St. Paul, Minnesota 55144-1000

March 11, 2022

Re: K200299
Trade/Device Name: Curos Jet Disinfecting Cap
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: Class II
Product Code: QBP

Dear Dianne Gibbs:

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 29, 2020. 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

October 29, 2020

3M Company
Dianne Gibbs
Regulatory Affairs Manager
2510 Conway Ave., Bldg. 275-5NW-06
St. Paul, Minnesota 55144-1000

Re: K200299
Trade/Device Name: Curos Jet Disinfecting Cap
Regulatory Class: Unclassified
Product Code: QBP
Dated: September 28, 2020
Received: September 29, 2020

Dear Dianne Gibbs:

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. 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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sapana Patel -S

Payal Patel
for Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200299

Device Name

Curos Jet™ Disinfecting Cap for Needleless Connectors – Single (CFJ1-270); Curos Jet™ Disinfecting Cap for Needleless Connectors – Strip (CFJ5-250)

Indications for Use *(Describe)*

The Curos Jet™ Disinfecting Cap is intended for use on needleless connectors only as a disinfecting cleaner prior to I.V. access and to act as a cover between line accesses. The cap will disinfect the needleless connector one (1) minute after application and protect from contamination between accesses for up to seven (7) days if not removed. The effectiveness of the cap was tested in vitro against Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata, and Candida albicans and was found to have >4 log reduction. The cap may be used in the home or healthcare facility.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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3M Company

3M Health Care
2510 Conway Ave., Bldg. 275-5W-06
St. Paul, MN 55144 U.S.A.
651 733 1110

510(k) Summary
3M™ Curos Jet™ Disinfecting Cap

General Company Information

Name: 3M Company
Contact: Cory J. Hitzman, Ph.D.
Regulatory Affairs Specialist
Address: 3M Company, 3M Health Care
2510 Conway Ave., Bldg. 275-5NW-06
St. Paul, MN 55144-1000
Telephone: (651) 733-9304
Fax: (651) 737-5320

Date Prepared

February 5, 2020

Subject Device

Trade Name: Curos Jet™ Disinfecting Cap
Regulation Number: Unclassified
Regulatory Class: Unclassified
Classification Name: Cap, Device Disinfectant
Classification Code: QBP
Classification Panel: General Hospital

Predicate/Reference Devices

Same regulatory classifications for Predicate/Reference Devices as the Subject Device above:
Predicate Device: K111992 – 3M™ Curos™ Disinfecting Cap
Reference Device: K121171 – 3M™ Curos Tips™ Disinfecting Cap

Device Description

The 3M™ Curos Jet™ Disinfecting Cap is a single use, sterile cap that contains 70% Isopropyl Alcohol and is intended to disinfect and protect needleless connectors. The Curos Jet™ Disinfecting Cap is translucent green in color. The device consists of a molded high-density polyethylene (HDPE) cap designed to fit onto female threads of a needleless connector, containing a HDPE plunger within. This plunger, when the cap is screwed onto a connector, travels towards a reservoir of 70% Isopropyl Alcohol, releasing it onto the needleless connector for disinfection. The Curos Jet™ Disinfecting Cap is offered in one size only, however it is packaged in “single” (1-cap) and “strip” (5-cap) configurations on a foil seal.

Intended Use (Indications)

The Curos Jet™ Disinfecting Cap is intended for use on needleless connectors only as a disinfecting cleaner prior to I.V. access and to act as a cover between line accesses. The cap will disinfect the needleless connector one (1) minute after application and protect from contamination between accesses for up to seven (7) days if not removed. The effectiveness of the cap was tested *in vitro* against *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata*, and *Candida albicans* and was found to have >4 log reduction. The cap may be used in the home or healthcare facility.

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St. Paul, MN 55144 U.S.A.
651 733 1110

Comparison with Predicate/Reference Devices

Characteristic	Subject Device	Predicate Device	Reference Device
Device Name	Curos Jet™ Disinfecting Cap	Curos™ Disinfecting Cap	Curos Tips™ Disinfecting Cap
Common Name	Cap, Device Disinfectant	Cap, Device Disinfectant	Cap, Device Disinfectant
510(k) #	Not Assigned	K111992	K121171
Manufacturer	3M Company	3M Company	3M Company
Regulation Number, Product Code	Unclassified, Pre-amendment device, product code: QBP	Unclassified, Pre-amendment device, product code: QBP	Unclassified, Pre-amendment device, product code: QBP
Indications for Use	The Curos Jet™ Disinfecting Cap is intended for use on needleless connectors only as a disinfecting cleaner prior to I.V. access and to act as a cover between line accesses. The cap will disinfect the needleless connector one (1) minute after application and protect from contamination between accesses for up to seven (7) days if not removed. The effectiveness of the cap was tested *in vitro* against *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata,* and *Candida albicans* and was found to have >4 log reduction. The cap may be used in the home or healthcare facility.	The Curos™ Disinfecting Cap is intended for use on swabbable 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, Pseudomonas aeruginosa, Candida glabrata* and *Candida albicans* and was found to have >4 log reduction. The Curos Port Protector may be used in the home or healthcare facility.	The Curos Tips™ disinfecting cap is intended for use as a disinfecting cleaner on male luer connections only and to act as a cover between line accesses. The Curos Tips disinfecting cap will disinfect the male luer one (1) minute after application and protect from contamination between accesses for up to seven (7) days if not removed. The effectiveness of Curos Tips disinfecting cap was tested *in vitro* against *Staphylococcus aureus, Staphylococcus epidermidis, Escherichia coli, Pseudomonas aeruginosa, Candida glabrata*, and *Candida albicans* and was found to have > 4 log reduction. The Curos Tip disinfecting cap may be used in the home or healthcare facility.
Connection Site	Needleless Luer Connectors	Needleless Luer Connectors	Male Luer Connections
Cap Materials	Molded Cap: HDPE Molded Plunger: HDPE	Molded Cap: HDPE Molded Insert: HDPE Foam: Polyurethane	Molded Cap: HDPE Molded Plunger: HDPE

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Characteristic	Subject Device	Predicate Device	Reference Device
Disinfectant – Active Ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	70% Isopropyl Alcohol
Minimum Disinfectant Time	One (1) Minute	Three (3) Minutes *(Data on File Supports One (1) Minute)*	One (1) Minute
Maximum Disinfectant Time	Seven (7) Days	Seven (7) Days	Seven (7) Days
Disinfectant Delivery	IPA Reservoir (via HDPE plunger compression)	IPA Reservoir (via foam sponge compression)	IPA Reservoir (via HDPE plunger compression)
Cap Length	0.46 inches	0.36 inches	0.78 inches
Cap Diameter	0.54 inches	0.54 inches	0.31 inches
Colorants Used	Translucent Green in molded HDPE, 3% concentration	Translucent Green in molded HDPE, 3% concentration	Translucent Green in molded HDPE, 3% concentration
Provided Sterile	Yes	Yes	Yes
Single Use Device	Yes	Yes	Yes
Plastic Housing to remain in place	Yes	Yes	Yes
User Population	Home and Hospital Use	Home and Hospital Use	Home and Hospital Use

Comparison of Technological Characteristics with the Predicate Device

The Subject Device and Predicate Device are both based on the same technological elements:

- Both are disinfectant caps for use with needleless connectors
- Both utilize IPA as the disinfectant
- Both are mechanically secured to the needleless connector
- Both are sterilized via gamma irradiation
- Both are indicated for home and hospital use

There are two functional characteristics that do differ when comparing the Subject Device to the Predicate Device (these characteristics do not differ when comparing to the Reference Device, demonstrating these changes are not novel):

- Minimum time required for disinfection:
  - Subject Device: 1 minute
  - Predicate Device = 3 minutes (data on file at 3M Company to support 1 minute)
  - Reference Device: 1 minute
- IPA disinfectant delivery:
  - Subject Device: HDPE Plunger compression
  - Predicate Device: Sponge compression
  - Reference Device: HDPE Plunger compression

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These differences in minimum time for disinfection and IPA disinfectant delivery do not affect the performance of the Subject Device, demonstrated through acceptable device functional, efficacy, biocompatibility, sterility, and packaging test results as described below.

Substantial Equivalence Performance Testing

3M Company has provided non-clinical performance test data for the Curos Jet™ Disinfecting Cap Subject Device that demonstrates the pre-defined acceptance criteria for a disinfecting device have been met. This acceptance criterion is defined as a ≥ 4 Log count reduction of two gram-negative bacteria (*Escherichia coli, Pseudomonas aeruginosa*), two gram-positive bacteria (*Staphylococcus aureus, Staphylococcus epidermidis*), and two fungi (*Candida glabrata, Candida albicans*), for one minute. The efficacy testing methodologies and microbes are the same as those tested for the Curos™ Disinfecting Cap Predicate Device cleared under 510(k) K111992 and the Curos Tips™ Disinfecting Cap Reference Device cleared under 510(k) K121171. The efficacy test results for the Subject Device over the three-year shelf life of the product are summarized below.

Subject Device Efficacy Test Results

Microorganism	Mean Log Reduction (1-Minute)	Mean Log Reduction (7-Day)
Candida albicans	5.25	5.25
Candida glabrata	4.53	5.46
Escherichia coli	4.57	4.94
Pseudomonas aeruginosa	5.03	5.55
Staphylococcus aureus	5.36	5.15
Staphylococcus epidermis	4.70	5.22

The Curos Jet™ Disinfecting Cap Subject Device cap and packaging performance has been tested to meet pre-specified requirements related to foil seal peel strength, cap retention force to needleless connectors, as well as cap compatibility with needleless connectors via pressure/vacuum leak testing. All testing was completed in accordance with approved company protocols and was completed to demonstrate that the Subject Device seals and acts as a cover for needleless connectors.

The Curos Jet™ Disinfecting Cap Subject Device is sterilized via gamma irradiation using a validated sterilization process which complies with ISO 11137-1:2006 (*Sterilization Of Health Care Products – Radiation – Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices*, FDA Recognition Number 14-528) and the VD_{max}^{25} method described in ISO 11137-2:2013 (*Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose*; FDA Recognition Number 14-409). Bioburden testing is in compliance with ISO 11737-1:2018 (*Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product*; FDA Recognition Number 14-514) while suitability of the sterility test methodology is in compliance with ISO 11737-2:2009 (*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*; FDA Recognition Number 14-327).

The Curos Jet™ Disinfecting Cap Subject Device sterile barrier foil lid complies with ISO 11607-1:2006 (*Packaging for Terminally Sterilized Medical Devices - Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems*; FDA Recognition Number 14-454). Packaging validation activities comply with ISO 11607-2:2006 (*Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes*; FDA Recognition Number 14-455). The packaging validation activities demonstrated the foil lid maintains product sterility, form, and function over the 3-year shelf life.

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Biocompatibility testing has been completed according to ISO 10993-1:2009 (*Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing*; FDA Recognition Number 2-220) to demonstrate the materials of construction for the Curos Jet™ Disinfecting Cap Subject Device are safe for their intended use and is substantially equivalent to the Predicate Device plus Reference Device. Due to the intended use of the product, the biocompatibility evaluation was completed as a surface device, skin contact, prolonged (< 30 days) exposure. According to FDA guidance and ISO 10993-1:2009, test results included cytotoxicity, sensitization, and irritation.

Clinical Evaluation:

The Curos Jet™ Disinfecting Cap Subject Device, as well as Curos™ Disinfecting Cap Predicate Device and Curos Tips™ Disinfecting Cap Reference Device, are all commercially available in the United States as well as in international markets and were originally classified according to product code LKB (Pad, Alcohol, Device Disinfectant), which was exempt from premarket notification. Therefore, several years of commercial product experience is available for the Subject Device as well as the Predicate Device and Reference Device. These products have since been reclassified to product code QBP (Cap, Device Disinfectant).

In support of the clinical performance of the Curos Jet™ Disinfecting Cap Subject Device, a review of commercial experience data is provided, comprised of publicly available literature plus product complaints data from the MAUDE database. The dataset supports the proven safety and effectiveness of the Curos Jet™ Disinfecting Cap Subject Device, when used as intended.

Conclusions

The analysis arguments and test results demonstrate the 3M™ Curos Jet™ Disinfecting Cap (Subject Device) is substantially equivalent to the 3M™ Curos™ Disinfecting Cap (Predicate Device).