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,

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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K200299 - 510(k) Summary

3M™ Curos Jet™ Disinfecting Cap for Needleless Connectors

General Company Information

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Regulatory Affairs Manager
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St. Paul, MN 55144-1000
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Date Prepared

October 29, 2020

Subject Device

Trade Name: 3M™ Curos Jet™ Disinfecting Cap for Needleless Connectors
Regulation Number: Unclassified
Regulatory Class: Unclassified
Classification Name: Cap, Device Disinfectant
Classification Code: QBP
Classification Panel: General Hospital

Predicate Device

Trade Name: 3M™ Curos™ Disinfecting Cap for Needleless Connectors
Regulation Number: Unclassified
Regulatory Class: Unclassified
Classification Name: Cap, Device Disinfectant
Classification Code: QBP
Classification Panel: General Hospital
510(k): K111992

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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.

Comparison with Predicate Device

Characteristic	Subject Device	Predicate Device	Comparison
Device Name	Curos Jet™ Disinfecting Cap for Needleless Connectors	Curos™ Disinfecting Cap for Needleless Connectors	
Common Name	Cap, Device Disinfectant	Cap, Device Disinfectant	
510(k) #	K200299	K111992	
Manufacturer	3M Company	3M Company	
Regulation Number, Product Code	Unclassified, Pre-amendment device, product code: QBP	Unclassified, Pre-amendment device, product code: QBP	

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Characteristic	Subject Device	Predicate Device	Comparison
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.	Substantially Equivalent *(Both subject and predicate devices are intended for use on the same types of needleless connectors. The predicate device has a three (3) minute minimum disinfection time while the subject device has a one (1) minute minimum disinfection time. The shorter disinfection time does not affect the safety or effectiveness of the subject device compared to the predicate device as demonstrated through acceptable device bench testing. Protection from contamination through 7 days remains the same for the subject and predicate device. The subject device was assessed via antimicrobial efficacy testing plus microbial barrier testing.)*
Connection Site	Needleless Luer Connectors	Needleless Luer Connectors	No Difference

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Characteristic	Subject Device	Predicate Device	Comparison
Cap Materials	Molded Cap: HDPE Molded Plunger: HDPE	Molded Cap: HDPE Molded Insert: HDPE Foam: Polyurethane	Substantially Equivalent *(Same HDPE materials. Predicate device polyurethane foam removed; subject device HDPE plunger included. Materials evaluated per ISO 10993-1.)*
Disinfectant – Active Ingredient	70% Isopropyl Alcohol	70% Isopropyl Alcohol	No Difference
Minimum Disinfectant Time	One (1) Minute	Three (3) Minutes	Substantially Equivalent *(The predicate device has a three (3) minute minimum disinfection time while the subject device has a one (1) minute minimum disinfection time. The antimicrobial efficacy test data demonstrates the subject device meets the acceptance criteria previously defined by the predicate device. The shorter disinfection time does not affect the safety or effectiveness of the subject device compared to the predicate device.)*
Maximum Disinfectant Time	Seven (7) Days	Seven (7) Days	No Difference

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Characteristic	Subject Device	Predicate Device	Comparison
Disinfectant Delivery	IPA Reservoir (via HDPE plunger compression)	IPA Reservoir (via foam sponge compression)	Substantially Equivalent *(Both subject and predicate device bathe connector with disinfectant for antimicrobial effect. Plunger performance evaluated via dimensional, physical and functional testing, plus antimicrobial efficacy and microbial barrier testing.)*
Cap Length	0.46 inches	0.36 inches	Substantially Equivalent *(Different lengths inherent to the design. Assessed as part of dimensional, physical and functional testing.)*
Cap Diameter	0.54 inches	0.54 inches	No Difference
Colorants Used	Translucent Green in molded HDPE, 3% concentration	Translucent Green in molded HDPE, 3% concentration	No Difference
Provided Sterile	Yes	Yes	No Difference
Single Use Device	Yes	Yes	No Difference
Plastic Housing to remain in place	Yes	Yes	No Difference
User Population	Home and Hospital Use	Home and Hospital Use	No Difference

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Discussion of Different Technological Characteristics

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

The Subject Device and Predicate Device are different with respect to the following items:

- Minimum time required for disinfection:
  - Subject Device: 1 minute
  - Predicate Device: 3 minutes

- IPA disinfectant delivery:
  - Subject Device: HDPE Plunger
  - Predicate Device: Sponge

- Cap Materials:
  - Subject Device: Molded Cap and Plunger made of HDPE
  - Predicate Device: Molded Cap and Insert made of HDPE; Foam: Polyurethane

- Cap Length:
  - Subject Device: 0.46 inches
  - Predicate Device: 0.36 inches

These differences do not affect the safety or effectiveness of the Subject Device compared to the Predicate Device, demonstrated through acceptable device functional, packaging, efficacy, biocompatibility, and sterility test results as described below. The cap length was increased to allow for easier handling of the device compared to the Predicate Device.

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Non-Clinical Testing

The following performance data were provided in support of the Curos Jet™ Disinfecting Cap Subject Device to internal test methods or standards:

- Luer Activated Valve Pressure/Vacuum Compatibility Testing
- Visual Inspection
- IPA Volume Testing
- Cap Retention to Foil Testing
- Foil Seal Peel Strength Testing
- Foil Seal Integrity Testing
- IPA Ingress/Alcohol Fluid Path Testing
- Microbial Barrier Performance Testing

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

Particulate testing was performed according to USP <788> (*Particulate Matter in Injections*) to demonstrate particulate levels for the Curos Jet™ Disinfecting Cap Subject Device meet USP <788> requirements.

3M Company provided antimicrobial efficacy test data for the Curos Jet™ Disinfecting Cap Subject Device that demonstrates the acceptance criteria previously defined by the Predicate Device have been met. This acceptance criterion for the Subject Device is defined as an average ≥ 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*), from 1 minute up to 7 days. The efficacy testing methodologies and microbes are the same as those tested for the Curos™ Disinfecting Cap Predicate Device cleared under 510(k) K111992. The antimicrobial efficacy test results for the Subject Device over the three-year shelf life of the product are summarized below.

Subject Device Antimicrobial Efficacy Test Results

Microorganism	Mean Log Reduction	
	1-Minute	7-Day
Candida albicans	5.07	5.25
Candida glabrata	4.81	5.46
Escherichia coli	5.43	4.94
Pseudomonas aeruginosa	4.87	5.55
Staphylococcus aureus	5.19	5.15
Staphylococcus epidermis	5.51	5.22

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Biocompatibility testing has been completed according to ISO 10993-1 (*Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing*) to demonstrate the materials of construction for the Curos Jet™ Disinfecting Cap Subject Device are safe for their intended use and substantially equivalent to the Predicate Device. Due to the intended use of the product, the biocompatibility evaluation was completed as an external communicating device, indirect blood path contact, prolonged (>24 hours to < 30 days) exposure. Test results included the following:

- ISO elution cytotoxicity per ISO 10993-5:2009
- Guinea pig maximization sensitization per ISO 10993-10
- Rabbit intracutaneous reactivity (irritation) per ISO 10993-10
- Rabbit material-mediated pyrogenicity per ISO 10993-11
- ASTM indirect hemolysis in rabbit blood per ISO 10993-4
- Acute systemic injection in mice per ISO 10993-11
- Subacute/subchronic toxicity in mice per ISO 10993-11

The Curos Jet™ Disinfecting Cap Subject Device is sterilized via gamma irradiation using a validated sterilization process which complies with ISO 11137-1 (*Sterilization Of Health Care Products – Radiation – Part 1: Requirements For Development, Validation And Routine Control Of A Sterilization Process For Medical Devices*) and the VD_{max}^{25} method described in ISO 11137-2 (*Sterilization of Health Care Products – Radiation – Part 2: Establishing the Sterilization Dose*). Bioburden testing is in compliance with ISO 11737-1 (*Sterilization of health care products – Microbiological methods – Part 1: Determination of the population of microorganisms on product*) while suitability of the sterility test methodology is in compliance with ISO 11737-2 (*Sterilization of medical devices – Microbiological methods – Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process*). The sterilization process for the Curos Jet™ Disinfecting Cap Subject Device provides a Sterility Assurance Level (SAL) of 10^{-6}.

Clinical Testing

Not applicable.

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Conclusions

The test results, meeting all performance requirements, demonstrate the differences between the 3M™ Curos Jet™ Disinfecting Cap for Needleless Connectors (Subject Device) and the 3M™ Curos™ Disinfecting Cap for Needleless Connectors (Predicate Device) do not raise any new or different questions of safety or effectiveness. The 3M™ Curos Jet™ Disinfecting Cap for Needleless Connectors (Subject Device) is substantially equivalent to the 3M™ Curos™ Disinfecting Cap for Needleless Connectors (Predicate Device) cleared under K111992 in intended use, target population, treatment method, use environment, and technological characteristics.