May 23, 2022

3M Company
Hilary Hovde
Regulatory Affairs Specialist
2510 Conway Ave.
Building 275-5W-06
St. Paul, Minnesota 55144

Re: K220507
Trade/Device Name: 3M™ Curos™ Tamper-Evident Device, 3M™ Curos™ Tamper-Evident Device, Large
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: Class II
Product Code: PZW, FPA, LJS
Dated: February 17, 2022
Received: February 22, 2022

Dear Hilary Hovde:

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,

David Wolloscheck
For Payal Patel
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220507

Device Name
3M™ Curos™ Tamper-Evident Device
3M™ Curos™ Tamper-Evident Device, Large

Indications for Use *(Describe)*

3M™ Curos™ Tamper-Evident Device:
The 3M™ Curos™ Tamper-Evident Device is intended to be used as a tamper-evident cover for vascular access devices for IV access points including needleless connectors and Y-sites on IV tubing. This device provides visual indication to suspect tampering. This is not a tamper-proof device.

3M™ Curos™ Tamper-Evident Device, Large:
The 3M™ Curos™ Tamper-Evident Device, Large is intended to be used as a tamper-evident cover on vascular access device needleless connectors including Y-sites on IV tubing, and infusing connections, providing visual indication of attempts to tamper with or remove the device. This device provides visual indication to suspect tampering. This is not a tamper-proof device.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K220507 - 510(k) Summary for 3M™ Curos™ Tamper-Evident Device

3M Company
2510 Conway Ave.
3M Center, Bldg. 275-5W-06
St. Paul, MN 55144-1000

Contact: Hilary B. Hovde
Regulatory Affairs Specialist
Phone Number: (651) 736-0364

Preparation Date: May 20, 2022

Device Name and Classification

Trade Name:	3M™ Curos™ Tamper-Evident Device 3M™ Curos™ Tamper-Evident Device, Large
Common/Usual Name:	Tamper-Resistant Catheter Access Cover
Device Classification:	Class II
Regulation Name/Number:	Percutaneous, implanted, long-term intravascular catheter [21 CFR § 880.5970, PZW]
Secondary Product Codes:	FPA, LJS

Predicate Device

PICCGuard, K191195, 21 CFR § 880.5970, PZW, Secondary Product Codes (LJS, FPA)

Indications for Use

3M™ Curos™ Tamper-Evident Device:

The 3M™ Curos™ Tamper-Evident Device is intended to be used as a tamper-evident cover for vascular access devices for IV access points including needleless connectors and Y-sites on IV tubing. This device provides visual indication to suspect tampering. This is not a tamper-proof device.

3M™ Curos™ Tamper-Evident Device, Large:

The 3M™ Curos™ Tamper-Evident Device, Large is intended to be used as a tamper-evident cover on vascular access device needleless connectors including Y-sites on IV tubing, and infusing connections, providing visual indication of attempts to tamper with or remove the device. This device provides visual indication to suspect tampering. This is not a tamper-proof device.

Description of Device

The 3M™ Curos™ Tamper-Evident Device provides visual indication to suspect tampering with or attempted removal of the device for reasons other than delivering prescribed medical treatment. The Tamper-Evident Device can be used on any type of vascular access device to cover needleless connectors and the Y-sites on IV tubing [with or without disinfecting caps]. The device material is transparent allowing for visualization of the connector(s) inside, and the tamper-evident strap is green allowing for easy visualization and assessment.
The 3M™ Curos™ Tamper-Evident Device is also provided in a larger size to accommodate larger needleless connector combinations including the Y-sites on IV tubing [with or without disinfecting caps] and infusing connections.

Comparison of Technological Characteristics with the Predicate Device

The 3M™ Curos™ Tamper-Evident Device was shown to be substantially equivalent to PICCGuard cleared per K191195. Any differences in technological characteristics such as materials and design differences were addressed through biocompatibility and performance testing. The biocompatibility and performance data demonstrated substantial equivalence. There were no new questions of safety and efficacy.

Feature	**Submission Device:** **3M™ Curos™ Tamper-Evident Device**	**Predicate Device (K191195):** **PICCGuard**	**Comparison**
Indications for use	The 3M™ Curos™ Tamper-Evident Device is intended to be used as a tamper-evident cover for vascular access devices for IV access points including needleless connectors and Y-sites on IV tubing. This device provides visual indication to suspect tampering. This is not a tamper-proof device. *3M™ Curos™ Tamper-Evident Device, Large:*	The PICCGuard device is indicated for use as a tamper evident enclosure for the shaft of the catheter and Luer hub with needleless connector attached on medical devices such as PICC lines and other central line catheter ports.	Both the submission and predicate devices are intended to provide tamper evidence of IV access points.

Feature	Submission Device: 3M™ Curos™ Tamper-Evident Device	Predicate Device (K191195): PICCGuard	Comparison
	The 3M™ Curos™ Tamper-Evident Device, Large is intended to be used as a tamper-evident cover on vascular access device needleless connectors including Y-sites on IV tubing, and infusing connections, providing visual indication of attempts to tamper with or remove the device. This device provides visual indication to suspect tampering. This is not a tamper-proof device.		
Use Environment	Hospitals and Clinics	Hospitals and Clinics	Identical
Patient Population	Patients requiring a vascular access device	Patients requiring a long-term central line catheter	Both the submission and predicate device are used with patients requiring vascular access devices.
Technological Characteristics	One-piece plastic housing with enclosing lid and green tamper-evident strap which is folded over lid of the device securing the latch inside the receiver to close. Available in two sizes to accommodate different size vascular access device combinations. Side door accommodates Y-site tubing. Designed with a tear strip that is used to open the device by	Two-piece plastic housing with locking barb. Available in one size. Entire PICC line fits inside of box for use. Medical scissors are used to disconnect	Differences in the design were evaluated through performance testing.

Feature	Submission Device: 3M™ Curos™ Tamper-Evident Device	Predicate Device (K191195): PICCGuard	Comparison
	breaking through the green tamper-evident strap when IV access is needed by the Health Care Professional. Tampering is indicated if the green tamper-evident strap has become separated, the tear strip is broken, or the device is missing.	the lid from the locked portion when IV access is needed by the Health Care Professional. Tampering is indicated if the PICCGuard is damaged or is missing from the IV line.	
Sterility	Non-sterile	Non-sterile	same

Discussion of Nonclinical testing

Bench testing and biocompatibility testing were completed to demonstrate substantial equivalence of the submission device, the 3M™ Curos™ Tamper-Evident Device, to the predicate device, PICCGuard.

The device performance was verified through the following tests:

Test	Results
Confirmation of Tamper-Evidence *Device exhibits signs of tampering*	Passed
Repeated Application and Removal of Device from IV lines *Catheter shows no sign of leakage after removal*	Passed
Removable by Design *Device can be removed from IV Line by single-use tear strip*	Passed

Biocompatibility

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process* as recognized by FDA. The 3M™ Curos™ Tamper-Evident Device is categorized as a surface contacting device, with intact skin contact of permanent duration (> 30 days) in accordance with ISO 10993-1 and FDA Guidance, *Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process."* The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Irritation

Clinical Tests

Not Applicable

Conclusion
Based on the intended use, technological characteristics, and performance data, the submission device is substantially equivalent to PICCGuard (cleared under K191195), Class II, product code PZW (subsequent product codes FPA, LJS) and does not raise new questions of safety and effectiveness.