March 27, 2026

SS Global
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
2552 Walnut Ave. Suite 230
Tustin, California 92780

Re: K254239
Trade/Device Name: CyClean Cord
Regulatory Class: Unclassified
Product Code: MVL
Dated: December 24, 2025
Received: December 29, 2025

Dear Priscilla Chung:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

MICHAEL E. ADJODHA -S

Michael E. Adjodha, MChE, RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K254239

Device Name
CyClean Cord

Indications for Use *(Describe)*
CyClean Cord is knitted retraction cord made from 100% lyocell, impregnated with Aluminum Chloride Hexahydrate for the temporary gingival retraction and hemostasis of the gingival margin.

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.

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510(k) Summary
(K254239)

This summary of 510(K) information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 3/26/2026

1. Submitter

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2. U.S Agent/Contact Person

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3. Device

- Trade Name: CyClean Cord
- Common Name: Gingival Retraction Cord
- Classification Name: Retraction Cord
- Product Code: MVL
- Classification regulation: Unclassified

4. Predicate Device:

Smartcord X by EASTDENT CO., LTD. (K171577)

5. Description:

The CyClean Cord is a dental gingival retraction cord containing aluminum chloride Hexahydrate in 100% lyocell knitted yarn, and is used to temporarily retract gingival tissue prior to obtaining a dental impression, and at the same time remove blood, saliva, and gingival fluid remaining in the gingival hotspots.

6. Indication for use:

CyClean Cord is knitted retraction cord made from 100% lyocell, impregnated with Aluminum Chloride Hexahydrate for the temporary gingival retraction and hemostasis of the gingival margin.

7. Basis for Substantial Equivalence

The subject device is substantially equivalent to the predicate device, Smartcord X of EASTDENT Co., Ltd (K171577).

Comparison Chart

	Subject Device	Predicate Device	Summary
Device Name	CyClean Cord	Smartcord X	-
Manufacturer	SS GLOBAL	EASTDENT CO., LTD.	-
510(k) Number	K254239	K171577	-
Classification Name	Retraction Cord	Retraction Cord	Same
Product Code	MVL	MVL	Same
Device Class	Unclassified	Unclassified	Same
Intended user	Dental professional	Dental professional	Same
Description	CyClean Cord is knitted retraction cord made from 100% lyocell, impregnated with Aluminum Chloride Hexahydrate.	Smartcord X is knitted retraction cord made from 100% cotton, impregnated with Aluminum Chloride Hexahydrate.	Similar
Indications for Use	CyClean Cord is knitted retraction cord made from 100% lyocell, impregnated with Aluminum Chloride Hexahydrate for the temporary gingival retraction and hemostasis of the gingival margin.	Smartcord is knitted retraction cord made from 100% cotton for the temporary gingival retraction. Smartcord X is knitted retraction cord made from 100% cotton, impregnated with Aluminum Chloride Hexahydrate for the temporary gingival retraction and hemostasis of the gingival margin.	Same
Raw Material	·Yarn : lyocell ·Hemostatic agent: Aluminum chloride hexahydrate ·Coloring agent	·Yarn : cotton ·Hemostatic agent: Aluminum chloride hexahydrate ·Coloring agent	Different.

Gingival Retraction Cord Type	Impregnated	Impregnated	Same
Body Contact	3 minutes	3 minutes	Same
Recommended contact time	3 minutes	3 minutes	Same
Color	· 000.0 : Charcoal · 000 : Purple · 00 : Dark green · 0 : Violet · 1 : Blue · 2 : Green	· 0^3 : black/gray · 0^2 : brown/yellow · 0 : purple/light purple · 1 : blue/light blue · 2 : green/light green	Different
Thickness	Model : Thickness(mm) 0.000 :0.51±0.1 000 :0.65±0.1 00 :0.74±0.1 0 :0.83±0.1 1 :0.95±0.1 2 :1.10±0.1	Model : Thickness(mm) 0^3 :0.70±5% 0^2 :0.82±5% 0 :0.89±5% 1 :1.20±5% 2 :1.31±5%	Similar
Length	254 cm / 100 inches	254 cm / 100 inches	Same
Biocompatibility	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Device is biocompatible when used as directed by dental professionals per ISO 10993-1.	Same
Sterilization	Non-sterile	Non-sterile	Same
Storage condition	Store in a dry, dark place between 1 and 35℃	Store in a dry, dark place between 1 and 35℃	Same
Shelf Life	3 years	3 years	Same

Substantial Equivalence Discussion

The subject device is the same as the predicate device in the intended use, design, and technological characteristics. There are differences in raw materials including dyes and thickness between the subject device and the predicate device. We performed biocompatibility test and various performance tests to support the substantial equivalence. Based on the test results and the information provided herein support that the subject device is substantially equivalent to the predicate device.

8. Non-Clinical Testing

The following tests were performed to support substantial equivalence.

No	Test Item	Test Standard
1	Appearance	-
2	Size	-
3	Packaging	-
4	Content of Aluminum Chloride Hexahydrate	-
5	Cytotoxicity Test	ISO 10993-5
6	Skin Sensitization Test	ISO 10993-10
7	Skin Irritation Test	ISO 10993-23
8	Acute Systemic Toxicity	ISO 10993-11

9. Conclusion

The subject device and the predicate device have the same intended use and have the same technological characteristics. Based on the similarities and the test results, we conclude that the subject device is substantially equivalent to the predicate device.