EASTDENT Co., Ltd
Hyonsu Kim
CEO
601-1 Sogong B/D, 64 Gugal-ro, Giheung-gu
Yongin-si, 16972 Korea

May 3, 2018

Re: K171577
Trade/Device Name: Smartcord, Smartcord X
Regulatory Class: Unclassified
Product Code: MVL
Dated: March 26, 2018
Received: April 3, 2018

Dear Hyonsu Kim:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Mary S. Runner -S

For 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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171577

Device Name
Smartcord, Smartcord X

Indications for Use *(Describe)*

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.

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.

510(K) SUMMARY

Smartcord, Smartcord X

Date: March 26, 2018

I. SUBMITTER

EASTDENT CO., LTD.
601-1, 64, Gugalro, Giheung-gu, Yongin-si, Gyeonggi-do, 16972, Korea

Tel: +82-31-693-5767
Fax: +82-31-693-5768

Contact Name: Hyonsu, Kim
Email: eastdent@east-dent.com

II. DEVICE

Name of Device:	Smartcord, Smartcord X
Regulation Name:	Retraction Cord
Classification Name:	Cord, Retraction
Regulatory Class:	Unclassified
Product Code:	MVL

III. PREDICATE DEVICE

K132526, Knit Pak plus / Knit Pak ™, Premier dental company products, Inc.

IV. DEVICE DESCRIPTION

Smartcord is non-impregnated knitted retraction cord made from 100% cotton.
Smartcord X is knitted retraction cord made from 100% cotton, impregnated with Aluminum Chloride Hexahydrate.

V. INDICATIONS FOR USE

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.

VI. COMPARISON OF TECHNILOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Smartcord

	Subject Device	Predicate Device	Summary
Device Name	Smartcord	Knit-Pak™	-
Manufacturer	EASTDENT CO., LTD.	Premier Dental Company Products	-
510(k) Number	New	K132526	-
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	Smartcord is non-impregnated knitted retraction cord made from 100% cotton.	Knit-Pak™ Gingival retraction cord is non-impregnated knitted cord made from 100% cotton.	Same
Indications for Use	Smartcord is knitted retraction cord made from 100% cotton for the temporary gingival retraction.	Not Listed	-
Raw material	Yarn : cotton Coloring agent	Yarn : cotton Coloring agent	Same
Gingival retraction cord Type	Non-Impregnated	Non-Impregnated	Same
Recommended contact time	3 minutes	Not Listed	-
Color	· 0^3 : black/gray · 0^2 : brown/yellow · 0 : purple/light purple · 1 : blue/light blue · 2 : green/light green	· 000 : Green · 00 : Brown · 0 : Purple · 1 : Blue · 2 : Orange	Different. But the retraction cords are available in various colors to be a dark to maximize

		· 3 : Yellow	contrast with the tissues, tooth, and cord.
Thickness	· 0^3 · 0^2 · 0 · 1 · 2	· 000 · 00 · 0 · 1 · 2 · 3	Different. But the retraction cords are available in various diameters(thickness) to accommodate variations in gingival anatomy.
Length	305 cm / 120 inches	254 cm / 100 inches	Different
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℃	Not Listed	-
Shelf Life	N/A	N/A	Same

Smartcord X

	Subject Device	**Predicate Device**	**Summary**
Device Name	Smartcord X	Knit-Pak+	-
Manufacturer	EASTDENT CO., LTD.	Premier Dental Company Products	-
510(k) Number	New	K132526	-
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	Smartcord X is knitted retraction cord made from 100% cotton, impregnated with Aluminum Chloride Hexahydrate.	Not Listed	-
Indications for Use	Smartcord X is knitted retraction cord made from 100% cotton, impregnated with Aluminum Chloride	Knit-Pak+ impregnated consists of a specialized design of knitted polyamide/polyester	Same

	Hexahydrate for the temporary gingival retraction and hemostasis of the gingival margin.	conjugated cord. This retraction cord is impregnated with Aluminum ChlorideHexahydrate and is intended for accurate and enhanced results when acquiring dental impressions, for cavity preparation or wherever hemostasis and retraction is required.	
Contents	Aluminum chloride hexahydrate(1.2mg±0.8mg/inch)	AlCl36H2O(0.5mg±0.1mg/inch)	Different. But the products consisting up to 15% Aluminum Chloride (Aluminum Chloride Hexahydrate) fall under the OTC monograph accepted by the FDA.
Raw material	Yarn : cotton Hemostatic agent : Aluminum chloride hexahydrate Coloring agent	Yarn : polyamide/polyester Hemostatic agent : Aluminum chloride hexahydrate Coloring agent	Different. Yarns are different, but hemostatic agent (Aluminum chloride hexahydrate) is the same.
Gingival retraction cord Type	Impregnated	Impregnated	Same
Body contact	Gingival sulcus	Gingival sulcus	Same
Recommended contact time	3 minutes	Not Listed	-
Color	· 0^3 : black/gray · 0^2 : brown/yellow · 0 : purple/light purple · 1 : blue/light blue · 2 : green/light green	· 000.0 : Dark Green · 000 : Green · 00 : Brown · 0 : Purple · 1 : Blue · 2 : Orange	Different. But the retraction cords are available in various colors to be a dark to maximize contrast with the tissues, tooth, and cord.
Thickness	· 0^3 · 0^2 · 0 · 1 · 2	· 000.0 · 000 · 00 · 0 · 1 · 2	Different. Retraction cords are available in various diameters (thickness) to accommodate variations in gingival anatomy.
Length	254cm / 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℃	Not Listed	-
Shelf Life	3 years	3 years	Same

VII. NON-CLINICAL PERFORMANCE TESTING

The biocompatibility evaluation for the Smartcord X device was conducted in accordance with the Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Guidance for Industry and Food and Drug Administration Staff, issued on: June 16, 2016, and international Standard ISO 10993-1 “Biological evaluation of medical devices - part 1: evaluation and testing within a risk management process” as recognized by FDA. The tests carried out for the devices and standards applied for each test are:

- Cytotoxicity, ISO 10993-5[2009]
- Oral mucous Irritation, ISO 10993-10[2010]
- Sensitization, ISO 10993-10[2010]

Smartcord X is considered to be in contact with gingival sulcus for duration of less than 24 hours, while being the external communicating device.

VIII. SUBSTANTIAL EQUIVALENCE DISCUSSION

The subject device consists of gingival retraction non-impregnated or impregnated cord, as is the predicate device. The subject device is same to predicate device in terms of classification name, product code, device class, indication for use, intended user, contents, raw materials, gingival retraction cord type, body contact, biocompatibility, sterilization, storage condition and shelf life.

There are no new ingredients or technology used on subject device. Their physical properties and performance of subject device are not significantly different from the predicate device, as indicated by non-clinical performance testing. The colors and thickness are different between subject device and predicate device. Differences of thickness and colors exist between the subject device and the predicate device.

However, these differences of colors and thickness do not influence(affect) its intended use for performance. Dentist select the thickness of retraction cord by the type and form of gingiva. The purpose of color use is only to distinguish the retraction cords from the gingiva, and the various colors is used for identification of the thickness to accommodate variations in gingival types and forms.

IX. CONCLUSIONS

The indications and technological characteristics of Smartcord X are very similar to predicate device. Therefore, Subject devices are substantially equivalent to the identified predicate device.