May 1, 2024

Smartooth Co., Ltd.
% Edward Park
CEO
LightenBridge LLC
4408 Tortuga Ln
McKinney, Texas 75070

Re: K231722
Trade/Device Name: SmarTooth
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: Class II
Product Code: NBL
Dated: April 2, 2024
Received: April 2, 2024

Dear Edward Park:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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.

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 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231722

Device Name
SmarTooth (Model: STL-02-BK)

Indications for Use *(Describe)*
For use as an aid in the diagnosis of dental caries

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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510(k) Summary – Traditional 510(k)

K231722

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR §807.92.

Submitter Information

Submitter Name:	Smartooth Co., Ltd.
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Contact Person:	Edward Park, official correspondent of Smartooth Co., Ltd.
Date of submission:	Sep 03, 2023

Device Information

Proprietary Name(s):	SmarTooth
Model Name:	STL-02-BK
Common Name:	Dental Monitoring Device
Regulation Name:	Laser Fluorescence Caries Detection Device
Product Code:	NBL
Regulation Number:	21 CFR 872.1745
Classification Panel:	Dental
Device Class:	II

Device Description

SmarTooth (STL-02-BK) is an optical dental caries diagnostic device that uses a laser to help diagnose dental caries. The SmarTooth (STL-02-BK) is composed of a portable hardware main body with batteries, a main body holder, and a mobile application. The hardware components provide a laser source, an LED indicator, and a zero point adjustment (calibration) unit to aid in the detection and monitoring of dental caries lesions in teeth. The software component provides a meter with a digital read-out between 0 and 99. The hardware device is a pen-type device consisting of a laser diode that generates a laser and a photodiode sensor to detect fluorescent light. Both the sensor and laser diode are mounted at the tip of the device to be introduced into the mouth of the patient for scanning of the teeth. The tooth is exposed to irradiation of a 650 nm wavelength laser by this device, and a value from the detected fluorescent light is displayed

to refer to the diagnosis of dental caries. The information from the scanner is handled by the Software, which holds the interface to the user.

As a battery-operated, portable laser source with a photodiode sensor, the subject device is designed for handheld operation. The dental probe is a replaceable, single-use component made from ABS material. This component is sized and dimensionally configured to achieve close contact with the tooth being examined. The tip ensures physical and optical contact with dentinal fluid at sites that are not readily accessible or evaluated using traditional means. The main body holder is used to calibrate the device before measuring the teeth.

The main body is powered by a 1.5-volt AA-type alkaline battery. This unit has two LED lamps (status and measurement), one power button, one laser output, and a beeper. The beeper sounds one time when pushing the power button for 1 second to turn on and 3 seconds to turn off the device. The main body should be paired with the zero point adjustment unit on the main body holder before use to calibrate the necessary optical zero point. Users can start the measurement by clicking the “Measure” button on the application screen.

Predicate Device

- KaVo DIAGNOdent® 2190 (KaVo Dental Corporation K051909, 10/21/2005)
  - Common Name: Laser fluorescence caries detection device
  - Regulation Name: Dental Hand Instrument, Laser Fluorescence Caries Detection Device
  - Device Class: II
  - Product Code: NBL
  - Regulation Number: 21 CFR 872.1745
  - Classification Panel: Dental

Indications for Use: For use as an aid in the diagnosis of dental caries.

Technological Characteristics

The SmarTooth (STL-02-BK) retains the same basic design components and operating features as the predicate device, KaVo DIAGNOdent® 2190 (K051909). The handheld device features a main body, disposable probe, main body holder, and mobile application. The laser diode and the battery pack are integrated into the main body. The functionality of the user interface is also similar to the predicate device. The power of both devices is supplied by one AA Alkaline battery. Both devices have 1.5 VDC. Testing has been completed on basic safety and essential performance, and the device complies with AAMI ES60601-1, IEC 60601-1-2, and IEC 60601-1-6.

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Device Name	**SmarTooth (STL-02-BK)**	**KaVo DIAGNOdent® 2190**	**Remark**
510k number		**K051909**	
Manufacturer	**Smartooth Co., Ltd.**	**KaVo Dental Corporation**	
Device Classification Name	Dental Hand Instrument, Laser Fluorescence Caries Detection Device	Dental Hand Instrument, Laser Fluorescence Caries Detection Device	Identical
Classification Product Code	NBL	NBL	Identical
Regulation Number	21 CFR 872.1745	21 CFR 872.1745	Identical
Regulation Class	II	II	Identical
Indications for Use	For use as an aid in the diagnosis of dental caries.	For use as an aid in the diagnosis of dental caries.	Identical
Principle of Operation	SmarTooth (STL-02-BK) emits red laser light of 650 nm onto a tooth surface. This wavelength causes porphyrins (colored protein molecules) in carious tissue to fluoresce, resulting in elevated scale readings on the display of the system. The presence of bacterial by-products is an indirect measure that caries are present. A scale of 1-99 with readings is available with a mobile application. Readings below 11 suggest a healthy tooth surface. Readings over 10 suggest the teeth require care and attention. Readings over 20 suggest the teeth is suspicious of caries.	DIAGNOdent emits red laser light of 655 nm onto a tooth surface. This wavelength causes porphyrins (colored protein molecules) in carious tissue to fluoresce, resulting in elevated scale readings on the display of the system. The presence of bacterial by-products is an indirect measure that caries are present. A scale of 1-100 with readings below 13 suggests a healthy tooth surface. Readings over 12 suggest the presence of caries in the dentin. Readings over 25 suggest the presence of caries into dentin requiring restoration.	Similar
Body Size	35.5mm(W)×34.4mm(D)×209mm(H)	30.0mm (Diameter) × 220mm (Length)	Similar

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Device Name	**SmarTooth (STL-02-BK)**	**KaVo DIAGNOdent® 2190**	**Remark**
510k number		**K051909**	
Manufacturer	**Smartooth Co., Ltd.**	**KaVo Dental Corporation**	
Weight	72.6g	110g	Similar
Light source	650nm, less than 1 mW laser	655nm, less than 1 mW laser	Similar
Returned light	Fluorescence (DC Luminescence)	Fluorescence (DC Luminescence)	Identical
Detectors for Returned Light	Photodiode for DC fluorescence	Photodiode for DC fluorescence	Identical
Sterilization	N/A (Probe tip is disposable)	Probe tip only, autoclavable	Different
User Interface	Power button, audible tones, LED lamp, mobile software for the control & display panel, calibration device, single probe.	Power button, numeric and audible tones, LCD display panel, calibration components, Fissure probe F, Prox probe A	Similar
Energy Source	1 AA Alkaline battery	1 AA Alkaline battery	Identical

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Discussion

A. Principle of Operation
The wavelength of the Smartooth's laser light is 650nm, whereas the predicate's is 655nm. Also, the scale of the Smartooth's output measuring scores is 1~99 on the mobile application, whereas the predicate's is 1~100 on the main hardware component. But the safety and efficacy of the subject device is evaluated through EMC and performance testing. Therefore, the difference doesn't raise new or different safety and effectiveness questions.

B. Body Size and Weight
Despite the difference in their body size and weight, both the Smartooth and the predicate device ensure ease of handling. Therefore, the weight and size difference between the two devices is negligible and does not raise any safety or effectiveness concerns.

C. Sterilization
The cleaning and sterilization method is different between the two devices. However, the Smartooth's cleaning and sterilization methods comply with the FDA guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, and the cleaning and disinfection methods have been validated in accordance with the standard, ASTM E2314-03; 2014 and AAMI TIR 30;2011/(R)2016, and AAMI TIR12;2020. Therefore, the difference in cleaning and disinfection between the two devices does not raise any safety or effectiveness concerns.

D. User interface
The user interface of Smartooth different from the predicate device includes LED lamp, and mobile software for the control panel. The usability assessment, Risk management, software validation, and cybersecurity have been evaluated for the differences. Therefore, the difference in user interface does not raise any safety or effectiveness concerns.

Performance Data

Non-clinical test was performed in accordance with the following international standards,

A. Electromagnetic Compatibility and Electrical Safety Test

- IEC 60601-1:2005+AMD1:2012+AMD2:2020, Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

- IEC 60601-1-2:2014, Medical Electrical Equipment – Part 1-2: General Requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010+AMD1:2013+AMD2:2020 for Use in conjunction with IEC 62366-1:2015, Medical Electrical Equipment – Part 1-6: General Requirements for safety – Collateral Standard: Usability

B. Biocompatibility Test

- ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro Cytotoxicity
- ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for Irritation

C. Performance Test - Bench

- Accuracy tests and safety for data transmission are performed.
- A non-clinical performance comparison test has been conducted.

D. Software Verification and Validation

- IEC 62304:2006+AMD1:2015, Medical Device Software – Software Life Cycle Processes
- IEC 62366 Ed.1.0:2007, Medical devices-Application of usability engineering to medical devices
- EN ISO 14971:2012, Medical devices - Applications of risk management to medical devices

Clinical testing was not necessary for the SmarTooth, based on the nature of the device (an 650 nm red laser light generator with photo diode). Adequate bench testing results should be sufficient in supporting our claim of substantial equivalence.

Conclusion

The subject device is substantially equivalent in indications for use, general functions & features, the principle of operation, and technological characteristics. The new device has a mobile application, but it does not affect safety and effectiveness without raising any issues. Therefore, we conclude that the subject device described in this submission is substantially equivalent to the predicate device.