May 17, 2024

Dental Monitoring SAS
Isabelle Puraye
Regulatory Affairs, Clinical Affairs, Quality Assurance Specialist
75 rue de Tocqueville
Paris, 75017
France

Re: DEN230035
Trade/Device Name: DentalMonitoring
Regulation Number: 21 CFR 872.1770
Regulation Name: Dental image analyzer
Regulatory Class: Class II
Product Code: SBC
Dated: May 4, 2023
Received: May 4, 2023

Dear Isabelle Puraye:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of DentalMonitoring, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> DentalMonitoring is a medical device software using image processing algorithms to analyze pictures of the oral cavity (hereinafter Scans). Scans are taken using the DM App, a smartphone, and the manufacturer's proprietary hardware products. Scans are taken by the patient, a non-healthcare professional, or a healthcare professional. The Scan is taken in healthcare facilities, such as a dental practice, or in a non-healthcare environment, such as the patient's own home. For some clinical parameters, DentalMonitoring requires a 3D Model. The product is designed to assist healthcare professionals in remotely monitoring orthodontic treatments and treatment progress. The results of DentalMonitoring are intended to be used as an aid in diagnosis and monitoring, not on a stand-alone basis for clinical decision-making. DentalMonitoring is indicated for use for patients over the age of 6 and reports results solely on permanent teeth.
>
> DentalMonitoring can monitor the following clinical parameters:
> - oral hygiene: dental plaque / food residue;
> - soft tissue statement: gingival recession, black triangle;
> - dental statement: closure of extraction space, tooth wear;
> - alignment: closure of all anterior spaces; and
> - dental occlusion:
>   - in 2D Monitoring: midline deviation, overbite/open bite, overjet
>   - in 3D Monitoring: canine class, midline deviation, overbite/open bite, overjet

Additionally, the following clinical parameters specific to orthodontic treatment types or phases can be monitored using DentalMonitoring:

- for aligner treatments: tracking (seat/unseat), attachment loss, button loss;
- for braces: bracket debonding, tie loss, self-ligating clips, passive archwire and auxiliaries; and
- for thermoformed retainers: tracking (seat/unseat).

Based on an initial 3D Model provided by a healthcare professional, DentalMonitoring can also provide healthcare professionals with 3D Models representative of the patient's dentition and treatment progress.

This device is a prescription device and is not intended for over-the-counter use

FDA concludes that this device should be classified into Class II. This order, therefore, classifies DentalMonitoring, and substantially equivalent devices of this generic type, into Class II under the generic name dental image analyzer.

FDA identifies this generic type of device as:

Dental image analyzer. A dental image analyzer is a prescription home use device that uses software intended to collect and analyze patient-specific, optical camera-based, intraoral images. The analyses are provided to dental health care professionals as an aid to diagnosis of oral health conditions and/or to monitor treatment progress.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On May 4, 2023, FDA received your De Novo requesting classification of DentalMonitoring. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify DentalMonitoring into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request FDA has determined that, for the previously stated indications for use, DentalMonitoring can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Risks to Health	Mitigation Measures
Adverse tissue reaction	Biocompatibility evaluation
Use error/ improper device use leading to incorrect oral health information conveyed to healthcare professional	Usability testing Labeling
Software malfunction leading to inaccurate patient monitoring and diagnosis	Software verification, validation, and hazard analysis
Device failure to adequately capture image or to identify or monitor the correct oral health condition leading to delayed treatment	Clinical performance data Non-clinical performance testing Software verification, validation, and hazard analysis

In combination with the general controls of the FD&C Act, the dental image analyzer is subject to the following special controls:

(1) Clinical performance data must demonstrate that the device performs as intended under anticipated conditions of use in the intended use population. Data must evaluate the accuracy and precision of diagnostic and monitoring device algorithms.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use. Validation testing must demonstrate that imaging hardware ensures adequate data for validated and accurate measurements. A description of the technical specifications of the hardware requirements must be included.

(3) The patient-contacting components of the device must be demonstrated to be biocompatible.

(4) Software verification, validation, and hazard analysis must be performed.

(5) Usability testing must demonstrate that the user can correctly use the device, based solely on reading the directions for use.

(6) Healthcare professional labeling and patient labeling must include the following:
   (i) Information on the analysis capabilities of the device, including clinical parameters and treatment plans;
   (ii) Information on how device reporting and functionality may change depending on the parameter or treatment;
   (iii) A detailed summary of the device technical parameters, including compatible operating systems, hardware, and/or accessories;
   (iv) Instructions for cleaning of any reusable components; and
   (v) A warning that the device is not intended to be used independently for diagnosis and that the device does not replace clinical decision making.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the dental image analyzer they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 1000-1050).

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Bobak Shirmohammadi at 301-796-3639.

Sincerely,

Kesia Alexander

for Malvina B. Eydelman, M.D.
Director
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health