February 22, 2024

Dentis Co., Ltd
Gyu Ri Kim
Researcher
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Daegu, 42718
SOUTH KOREA

Re: K233544
Trade/Device Name: Mesheet
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: November 3, 2023
Received: November 3, 2023

Dear Gyu Ri 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 (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 E. Adjodha, MChE, RAC, CQIA
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DHT1B: Division of Dental and
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OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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.

Submission Number *(if known)*

K233544

Device Name

MESHEET

Indications for Use *(Describe)*

The MESHEET is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

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

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Device Information

- Trade Name: MESHEET
- Common Name: Dental Plastic Aligners
- Classification Name: Orthodontic Plastic Brackets – Sequential Aligners
- Product Code: NXC
- Panel: Dental
- Regulation Number: 21 CFR 872.5470
- Device Class: Class II
- Prepared Date: 02/22/2024

Predicate Devices:
K222619, Ensmile by Ensmile Pvt Ltd.

Reference Device:
K192847, AUTOLIGN by Diorco Co., Ltd.

Indications for Use:
The MESHEET is indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Device Description:
MESEEHT is a thermoplastic aligner designed according to the patient to help maintain teeth to the final desired position. This MESHEET is to be removed for eating and for cleaning.

MESHEET is sequence of transparent aligner manufacture from digital scan/plan.

Each aligner delivers a unique combination of minor forces to create the planned tooth movement. MEHSEET has a main layer that material is poly ethylene and mesh layer that material is thermoplastic polyurethane. Among the main layer, mesh layer is added.

Technical Characteristics

MESEEHT has same technical Characteristics with predicate device(K222619) as manufacture by thermoplastic polymer to create a customized aligner. Subject device and predicate device are thermoformed by and outside laboratory.

A professional prescribes the MESHEET based on and assessment of the patient's teeth, determines a course of treatment with the system. To obtain the dimensions and details of a patient's dentition, a dentist use a commercial scanner, software, printer and model material. The model is fabricated and scanned. Scanned data are directly imported into dental design software for planning. Professional designs the process of treatment by creating a series of the sequential model intended to gradually move the patient's teeth to the desired position in accordance with the dentist's prescription utilizing the dental design software. The doctor reviews and approves the treatment scheme. Professional fabricates a series of models for thermoforming.

When a model is produced, MESHEET produces the orthodontic appliances formed of clear, thin, thermoformed plastic. The aligners provide gentle continuous force to move the patient's teeth in small increments from their original positions to planned positions. MESHEET aligner is held in place by pressure and can be removed by the patient at any time.

Non-Clinical Testing

MESHEET passed all the testing in accordance with standards shown below to support substantial equivalence of the subject device:

- Biocompatibility tests such as cytotoxicity, irritation, sensitization, Acute systemic toxicity, Bacterial reverse mutation, In vitro chromosome aberration, Intramuscular tests were performed in accordance with ISO 10993-1.

- OTS software validation test used to fabricate this subject device was performed according to Guidance for Industry and FDA Staff, Off-The Shelf Software Use in Medical Device. A performance qualification of the available software utilized in the processing steps of the subject device has been included to support substantial equivalence.

- Manufacturing Process Validation Testing
  This test was conducted to validate the manufacturing process of the final product. It evaluated the fit, form, and function of the final product by a trained physician as compared to software treatment design. This test has met the pre-established acceptance criteria. The test results showed that the manufacturing process of the subject aligner achieves its intended use, and it is substantially equivalent to the predicate devices.

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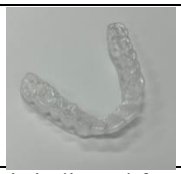
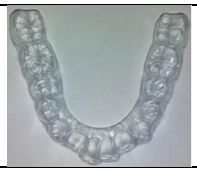
Substantial Equivalence Comparison

The subject device MESHEET is substantially equivalent to predicate device in intended use, material and technical characteristics. Comparison demonstrating Substantial Equivalence follows:

	Subject Device MESHEET	**Primary Predicate Ensmile**
Manufacturer	Dentis Co., Ltd	Ensmile Pvt Ltd
Regulation	21 CFR 872.5470	21 CFR 872.5470
Classification	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket
Product Code	NXC	NXC
Device Class	Class II	Class II
K number	N/A	K222619
Design		
Indication for Use	The MESHEET is indicated for the alignment of teeth during orthodontic treatment of malocclusion.	Ensmile is indicated for the alignment of teeth during orthodontic treatment of malocclusion.
Device Description	MESEEHT is sequence of transparent aligners created from a digital orthodontic treatment plan and thermoplastic aligners designed according to the patient to help maintain teeth to the final desired position. This MESHEET is to be removed for eating and for cleaning. MESHEET is sequence of transparent aligner manufacture from digital scan/plan. The digital orthodontic treatment plan is created by a dental health professional. Each aligner delivers a unique combination of minor forces to create the planned tooth movement. MESHEET has cross shape holes. MEHSEET has main layer that material is poly ethylene and mesh layer that material is thermoplastic polyurethane. Among the main layer, mesh layer is added.	The Ensmile is a sequence of transparent aligners created from a digital orthodontic treatment plan. The Ensmile aligner is fabricated of a transparent thermoformed polyurethane plastic. Each aligner delivers a unique combination of minor forces to create the planned tooth movement. The digital orthodontic treatment plan is created by a dental health professional. The Ensmile Aligner incorporates the use of attachments to create spaces and force points in order to cause minor tooth movement. These force points are located in specific areas and positioned in such a way that they provide a continuous force which slowly dissipates over time on the tooth to be moved for as long as the aligner is worn.
Mode of Action	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic tooth movement occurs through forces applied by the appliance to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.
Anatomy Location	Mouth; mucosal	Mouth; mucosal
Size	Patient Specific	Patient Specific
Manufacturing Method	Thermoforming	Thermoforming
Material	Thermoplastic Polymer	Thermoplastic Polymer
Software Used for Ordering	Yes	Yes
Substantial Equivalence Comparison	MESHEET has the same indication for use, manufacturing method, fundamental scientific technologies, principle of operation, material and similar design with the identified primary predicate device. There are no difference between our subject device and primary predicate. Therefore, MESHET is substantially equivalent with primary predicate.	

Conclusion

The MESHEET moves teeth by way of continuous gentle force through a sequence of clear aligners that follow the treatment plan developed by the clinician as does the primary predicate device, Ensmile Aligner.

The conclusions drawn from the data included in this submission, demonstrates that the subject device, MESHEET is substantially equivalent to the primary predicate device in indications for use, design, technological characteristics, mechanism of action, performance, materials and biocompatibility.