3D Global Biotech Inc
% Diana Lam
Regulatory Affairs Specialist
370 W Grand Blvd #110
Corona, California 92882

Re: K212803
Trade/Device Name: DailyMate Orthodontic Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: February 22, 2022
Received: February 22, 2022

Dear Diana Lam:

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. 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 located 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.

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) 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 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 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,

For Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K212803

Device Name
DailyMate Orthodontic Aligner System

Indications for Use *(Describe)*
The DailyMate Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.

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

K212803

Applicant:

3D Global Biotech Inc.

- Address: 21F.-3, No.99, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan
- Contact: Dr. Keng-Liang Ou, President
- Telephone: +886-2-26971270

Correspondent Contact:

Diana Lam,

370 W. Grand Blvd, Suite 110, Corona, CA 92882

Date Summary Prepared:

May 6th, 2022

DEVICE NAME: DailyMate® Orthodontic Aligner System

TRADE NAME: DailyMate® Orthodontic Aligner System

COMMON NAME: Aligner, Sequential

DEVICE CLASSIFICATION Name: Orthodontic Plastic Bracket

CLASSIFICATION REGULATION NUMBER: 21 CFR 872.5470
DEVICE CLASSIFICATION: CLASS II
CLASSIFICATION PRODUCT CODE: NXC

Predicate Device

Primary Predicate	SureCure Orthodontic Aligner System	K182329	Digital Orthodontic Care
Reference Device	Invisalign System	K143630	Align Technology, Inc.
Reference Device	3Shape Ortho System ™	K152086	3Shape A/S

Indications for Use

The DailyMate® Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.

Description of Device

The DailyMate® Orthodontic Aligner System is a series of dental aligners fabricated of clear, plastic removable aligners. The aligners are designed and custom-made by dental professionals. The aligners are made of aesthetic and medical grade materials. Corrective force to straighten the teeth is delivered via minor changes into a modified position in each subsequent aligner.

Substantial equivalence

The DailyMate® Orthodontic Aligner System is substantially equivalent to the predicate device and the reference device with respect to indications for use, mechanism of action and materials…… as demonstrated in the comparison table below.

Item Name	Subject device	Predicate Device	Predicate Device	Substantial equivalence Analysis
Device name	DailyMate® Orthodontic Aligner System	SureCure Orthodontic Aligner System	Invisalign System	
Manufacturer	3D Global Biotech Inc.	Digital Orthodontic Care	Align Technology, Inc.	-
510(K) No.	K212803	K182329	K143630	-
Regulation No.	21 CFR 872.5470	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Regulatory Class	Class II	Class II	Class II	Same
Product Code	NXC	NXC	NXC	Same
Indications for use/Intended use	The DailyMate Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.	The SureCure Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition. The aligner system repositions teeth by way of continuous gentle force.	The Invisalign System is indicated for the alignment of teeth during orthodontic treatment of malocclusion	Same as the predicate device
Mechanism of Action	Based on the clinician's treatment plan, each aligner is used for a defined period of time to exert	Based on the clinician's treatment plan, each aligner is used for a defined period of time to exert gentle force to achieve progressive	Sequential aligners apply continuous gentle force to the teeth	Same

	gentle force to achieve progressive realignment of the teeth. This occurs over time until the final correction has been achieved.	realignment of the teeth. This occurs over time until the final correction has been achieved.		
Method of Use	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Each preformed plastic tray is worn by the patient as prescribed by the dental practitioner, usually a few weeks prior to using the next sequential aligner tray.	Aligners are worn for approximately 2 weeks of 20-22 hours of wear per day, after which it is replaced by the next stage aligners. This is repeated for duration as prescribed by the Dental Practitioner	Same as the predicate device
Method of Manufacture	Using software, molds/models are 3D printed based on the treatment plan. Aligners are fabricated on the molds using a thermoforming machine.	Using software, molds/models are 3D printed based on the treatment plan. Aligners are fabricated on the molds using a thermoforming machine.	The Align 3-D Software uses a scan of a PVS impression or a digital scan (which represents an untreated state) to generate the image of a final, treated state and then interprets a series of images that represent intermediate teeth states. The dental practitioner then reviews these images and has the option to reject or request modifications to the set-up prior to approving it for aligner fabrication. Once the dental practitioner	Same as the predicate device

			approves the treatment plan, the software converts the files to produce the series of custom-made aligners	
Raw Material Used	Thin thermoformed polyurethane	Thin thermoformed polyurethane	Thin thermoformed polyurethane	Similar
OTC or Rx	Rx	Rx	Rx	Same
Software Use	3Shape Ortho System	3Shape Ortho System	Invisalign System 3-D software	Same as the predicate device
Sterilization	No	No	No	Same

The DailyMate® Orthodontic Aligner System is substantially equivalent to the predicate device and the reference device. Both the subject and predicate devices use the same 510(k) cleared dental software 3Shape Ortho System (K152086) to translate tooth movements in developing the model schemes and allow the dental practitioner to review and approve the model schemes before aligner fabrication.

The bench tests using both the DailyMate® Orthodontic Aligner System and the Invisalign System were performed, the results of pH change test, water absorption change test and tensile strength change test showed that the DailyMate® Orthodontic Aligner System and the Invisalign System were substantial equivalent.

The differences among the subject device, the predicate device and the reference device lie in the variances in the aligner treatment plans which were customized for each individual patient. The associated risks have been mitigated by (1) A 510(k) regulated broadly recognized dental software, 3Shape Ortho System, is used for aligner design and review. (2) Every treatment plan receives a certified dental practitioner' approvals before aligners were manufactured. (3) The manufacturer is an ISO13485 certified facility which follows GMP standards during the manufacturing processes.

Non-Clinical performance Data

The DailyMate® Orthodontic Aligner System uses polyurethane as the raw material, same as the predicate device and reference device. The DailyMate® Orthodontic Aligner System is a device contacts mucosal membrane for a duration of greater than 30 days. The biocompatibility testing for the aligner materials was completed in accordance with ISO 10993 per the following:

- Part 5: Cytotoxicity Test
- Part 10: Sensitization Test
- Part 10: Oral Mucosa Irritation Test

The testing results demonstrate that the material of DailyMate® Orthodontic Aligner System is biocompatible for the intended use.

The laboratory testing data was provided to confirm the quality of the DailyMate® Orthodontic Aligner System. A manufacturing validation report was also included to assure the substantial equivalence of the DailyMate® Orthodontic Aligner System.

Clinical performance Data

No clinical data was provided in this submission

Conclusion

The data included in this submission demonstrates that the DailyMate® Orthodontic Aligner System is substantially equivalent to the predicate device and the reference device in indications for use, mechanism of action, aligner design process, raw material and manufacturing fabrication process.