September 30, 2019

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

Re: K191774
Trade/Device Name: SmileAlign Orthodontic Aligner System
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: NXC
Dated: July 2, 2019
Received: July 2, 2019

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 Srinivas Nandkumar, Ph.D.
Acting Director
DHT1B: Division of Dental 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K191774

Device Name
SmileAlign® Orthodontic Aligner System

Indications for Use *(Describe)*
The SmileAlign® Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The SmileAlign Orthodontic Aligner System positions 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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K191774 - 510(k) Summary

Applicant:

3D Global Biotech Inc.

Address: 21F-1, No.99, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan

Telephone: +886-2-26971270

Correspondent Contact:

Diana Lam,

DuoCare, LLC

info@duocarepro.com

Date Summary Prepared:

Semptember 30, 2019

DEVICE NAME: SmileAlign® Orthodontic Aligner System

TRADE NAME: SmileAlign® 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	Byte Aligner System	K180346	Straight Smile, LLC
Reference Device	3Shape Ortho System ™	K152086	3Shape A/S

Description of Device

The SmileAlign® Orthodontic Aligner System is a series of dental aligners fabricated of clear, thin thermoformed polyethylene terephthalate glycol (PETG) plastic to progressively reposition the teeth. Corrective force to straighten the teeth is delivered via minor changes into a modified position in each subsequent aligner.

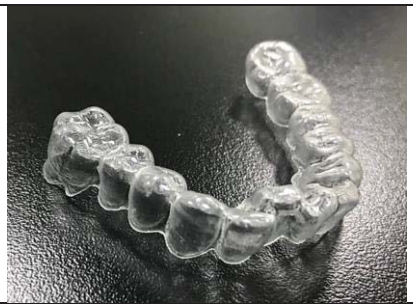
Indications for Use

The SmileAlign® Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The SmileAlign® Orthodontic Aligner System positions teeth by way of continuous gentle force.

Substantial equivalence

The SmileAlign® Orthodontic Aligner System is substantially equivalent to the predicate device with respect to indications for use, technological characteristics, principles of operation and materials…… as demonstrated in the comparison table below.

Item Name	Subject device	Predicate Device	Substantial equivalence Analysis
Device name	SmileAlign® Orthodontic Aligner System	Byte Aligner System	-
Manufacturer	3D Global Biotech Inc.	Straight Smile, LLC	-
510(K) No.	-	K180346	-
Regulation No.	21 CFR 872.5470	21 CFR 872.5470	Same
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	Same
Regulatory Class	Class II	Class II	Same
Product Code	NXC	NXC	Same
Indications for use	The SmileAlign® Orthodontic Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The SmileAlign® Orthodontic Aligner System positions teeth by way of continuous gentle force.	The Byte Aligner System is indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e., all second molars). The Byte Aligner System positions teeth by way of continuous gentle force.	Same
Intended Population	Individuals with permanent dentition	Individuals with permanent dentition	Same
Mode of Action	Orthodontic tooth movement occurs through forces applied by the device 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 device to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Same
Mode of Use	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as prescribed by a Dental	Each aligner is worn by the patient as determined by the treating dental practitioner, generally for 2 weeks prior to being replaced by the next aligner in sequence. This is repeated for a duration as	Same

	Professional.	prescribed by a Dental Professional.	
Raw Material Used	Thermoplastic polymers (polyethylene terephthalate glycol or PETG)	Thermoplastic polymers (polyethylene terephthalate glycol or PETG)	Same
OTC or Rx	Rx	Rx	Same
Design			Same

The SmileAlign® Orthodontic Aligner System is substantially equivalent to the predicate device. Both the subject and predicate devices use independent dental software 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 difference between the subject and predicate device lies in the difference in manufacturer, where the risks have been mitigated by biocompatibility evaluation and material testing. SmileAlign® Orthodontic Aligner System uses 3Shape Ortho System™ (K152086), the reference predicate, as the software for dental professionals to generate and review model schemes.

Non-Clinical performance Data

Different biocompatibility tests in accordance with ISO10993 have been performed on the subject device. The results of these tests and studies indicate there is no evidence of any hazardous effects and the subject device is safe for its intended use.

Test Name	Standard followed	Result
Cytotoxicity	ISO10993-5	Pass
Irritation	ISO10993-10	Pass
Sensitization	ISO10993-10	Pass

Material properties, such as tensile strength, compression strength, water absorption rate, density and pH change were tested, all results provided reasonable assurance of safety and effectiveness.

Clinical performance Data

Clinical data was not included in this submission.

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Conclusion

The SmileAlign® Orthodontic Aligner System has substantially equivalent Indications for Use and technological characteristics to the previously cleared predicate device Byte Aligner System (K180346). The conclusions drawn from the data included in this submission demonstrate that SmileAlign® Orthodontic Aligner System is substantially equivalent to the predicate devices in indications for use, design, technological characteristics, mode of action, method of use, performance, materials, and biocompatibility.