September 20, 2021

Biotech Dental Smilers, SAS
% Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K212961
Trade/Device Name: Smilers
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic plastic bracket
Regulatory Class: Class II
Product Code: NXC
Dated: September 15, 2021
Received: September 16, 2021

Dear Prithul Bom:

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,

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K212961

Device Name
SMILERS®

Indications for Use *(Describe)*
Biotech Dental SMILERS®aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e., all second molars) during orthodontic treatment of malocclusion. SMILERS®aligners position 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K212961

510(k) Summary
Biotech Dental
SMILERS®
9/6/2021

ADMINISTRATIVE INFORMATION

Manufacturer Name		Biotech Dental Smilers, SAS 305, Allée de Craponne 13300 Salon de Provence
	Telephone:	+33 04 90 44 60 60
	Fax:	+33 04 90 44 60 61
	Official Contact:	Delphine Mercier, VP Compliance
	Email:	d.mercier@biotech-dental.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name:	SMILERS®
Common Name:	Aligners, sequential
Classification Name:	Orthodontic Plastic Bracket
Classification Regulations:	21 CFR 872.5470
Device Class:	Class II
Product Code:	NXC
Review Panel:	Dental Products Panel
Reviewing Branch:	Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices (OHT1) Dental Devices (DHT1B)

PREDICATE DEVICE INFORMATION

The devices within this submission are the same or highly similar in indications, intended use and design principles to the following predicate device:

510(k)	Predicate Device Name	Company Name
K180346	Byte Aligner System	Straight Smile, LLC

DEVICE DESCRIPTION

The Biotech Dental SMILERS® aligners are a series of prescription-only clear plastic removable aligners intended to incrementally move a patient's teeth from an initial position to a different end position using a software-generated sequence of intermediate states. Biotech Dental SMILERS® sequentially reposition teeth by way of continuous gentle force.

Special orthodontic aligner treatment planning software, such as Nemocast (K193003) is used to virtually segment and reposition teeth to their desired position for each stage of treatment.

The technology and overall process is the same as that used by the Predicate device, Byte Aligner System (K180346) and other sequential aligner systems currently being legally-marketed.

INTENDED USE / INDICATIONS FOR USE

Biotech Dental SMILERS® aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e., all second molars) during orthodontic treatment of malocclusion. SMILERS® aligners position teeth by way of continuous gentle force.

EQUIVALENCE TO MARKETED DEVICE

The table below compares Indications for Use and Technological Characteristics of the Subject device and Predicate devices.

Predicate Device Comparison Table

Parameter	**Subject Device** SMILERS® Biotech Dental Smilers, SAS	**Predicate Device** Byte Aligner System Straight Smile, LLC K180346	**Comparison**
Regulation #	21 CFR 872.5470	21 CFR 872.5470	***Same***
Classification Name	Orthodontic Plastic Bracket	Orthodontic Plastic Bracket	***Same***
Product Code	NXC	NXC	***Same***
Classification	Class II	Class II	***Same***
Intended Use/ Indications for Use	Biotech Dental SMILERS® aligners are indicated for the alignment of teeth in patients with permanent dentition (i.e., all second molars) during orthodontic treatment of malocclusion. SMILERS® aligners position 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.	***Highly Similar***
Intended Population	Individuals with permanent dentition.	Individuals with permanent dentition.	***Same***
Mode of action	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	Orthodontic movement occurs through continuous gentle forces applied to the dentition as each tooth follows the programmed displacement based on a doctor's prescription.	***Same***
Method 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 Professional.	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 Professional.	***Same***
Material	Thermoplastic polymer (polyethylene terephthalate glycol or PETG)	Thermoplastic polymers (polyethylene terephthalate glycol or PETG)	***Same***
Appliance Application	Removable	Removable	***Same***
Design			***Highly Similar***
Biocompatible	Yes	Yes	***Same***
OTC or Rx	Rx	Rx	***Same***
Sterile	Non-sterile	Non-sterile	***Same***

The wording of the Indications for Use statements differs only in the device name.

TECHNOLOGICAL CHARACTERISTICS

Orthodontic tooth movement occurs through forces applied to the teeth by the appliance as each tooth follows the predetermined displacement based on a dental health professional's prescription. The Subject device mode of action, method of use and intended patient population are the same as the Predicate device and supports a determination of substantial equivalence.

The Subject and Predicate devices are both fabricated of non-sterile, biocompatible thermoplastic PETG material which supports a determination of substantial equivalence.

NON-CLINICAL PERFORMANCE TESTING

Due to the difficulty in evaluating this type of dental device in a laboratory environment, no direct performance bench testing of the aligners was performed. The use of thermoplastic materials for sequential aligners intended to treat malocclusions have been well documented in scientific literature regarding incremental tooth moving forces.

A manufacturing validation was performed which demonstrated the dimensional accuracy of the manufacturing process for SMILERS®. Using Nemocast software (K193003), cases were planned and the standard manufacturing process used to produce aligners from the treatment plans. The manufacturing validation evaluated dimensional accuracy of manufacturing aids as well as the final finished device. Additionally, a fit validation was performed where treatment planned and manufactured aligner cases were qualitatively evaluated by a qualified individual to determine if the Subject device performs as intended.

A shelf-life/aging study was performed to assess the impact of time-dependent material degradation within the stated shelf-life of the device.

Biocompatibility evaluation and testing for the aligner material was conducted in accordance with International Standard ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process". A chemical characterization was performed according to ISO 10993-18:2020.

The following biological tests were performed:

Biological Endpoint	**Relevant Standard**
Cytotoxicity	ISO 10993-5:2009
Sensitization	ISO 10993-10:2010
Irritation	ISO 10993-10:2010
Endotoxins	ANSI/AAMI ST72:2019

Non-clinical performance testing of the Subject device met the acceptance criteria for each validation and test described above. This non-clinical performance testing demonstrates that the Subject device is suitable for intended use as was also done for the Predicate device.

CLINICAL TESTING

The performance of sequential aligners in the clinical environment has been well established since the first such devices were cleared by the FDA in 1998 under product code NXC. No clinical data is included in this submission.

CONCLUSION

Overall, the Indications for Use statement for the Subject and Predicate devices are highly similar differing only in device name. Overall, the Technological Characteristics of the Subject device are the same or highly similar to the Predicate device with any differences mitigated through non-clinical performance testing.