July 20, 2021

Wade Munsch, Regulatory Affairs Manager
Biotex, Inc.
114 Holmes Rd.,
Houston, Texas 77045

Re: K203712
Trade/Device Name: The Slide
Regulation Number: 21 CFR 872.5570
Regulation Name: Intraoral Devices For Snoring And Intraoral Devices For Snoring And Obstructive Sleep Apnea
Regulatory Class: Class II
Product Code: LQZ, LRK
Dated: January 19, 2021
Received: January 19, 2021

Dear Wade Munsch:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203712

Device Name
The Slide

Indications for Use *(Describe)*
The Slide is for use to reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

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.

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

1. SUBMITTER

Biotex, Inc.
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Email: wade.munsch@biotexmedical.com
Contact Person: Wade Munsch
Date Prepared: July 19th, 2021

2. DEVICE

Name of Device:	The Slide
Classification Name:	Device, Anti-Snoring
Regulation:	21 CFR §872.5570
Regulatory Class:	Class II
Product Classification Code:	LQZ, LRK
510(k):	K203712

3. PREDICATE DEVICE

Predicate Manufacturer:	Somnomed
Predicate Trade Name:	Somnodent G2
Predicate 510(k):	K121340

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

4.1. The Slide™ is a prescribed intraoral device worn while sleeping in order to reduce nighttime snoring and mild to moderate obstructive sleep apnea (OSA). Snoring and OSA is caused by partial or complete closure of the muscle in the upper airway (pharyngeal space). The device uses two splints joined by two parallel sliding connectors that position the lower jaw forward and open from its normal location. This forward protrusion opens up the upper airway reducing obstructions during sleep. The prescribing dentist determines the exact repositioning of the lower bite. Its simplistic design allows for the forward displacement to be adjusted without the use of specialized tools using different sized spacers. Adjustments are initially made in the prescribing dentist office; further adjustments can be made depending on relief of symptoms and comfort while sleeping.

5. INDICATIONS FOR USE

5.1. The Slide is for use to reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

6.1. The following characteristics were compared between the subject device and the predicate device in order to demonstrate substantial equivalence:

Table 1: Comparison of The Slide with SomnoDent G2 (K121340).

	The Slide K203712	SomnoDent G2 – K121340	Evaluation of Differences
Indication for Use	The Slide is for use to reduce night-time snoring and mild to moderate obstructive sleep apnea (OSA) in adults.	The SomnoDent G2 is intended for the treatment of nightime snoring and mild to moderate obstructive sleep apnea in patients 18 years of age or older.	N/A
Intended Use			
Intended as intraoral device	Yes	Yes	N/A
Intended to reduce snoring or help alleviate snoring	Yes	Yes	N/A
Intended for treatment of mild to moderate obstructive sleep apnea	Yes	Yes	N/A
Intended for nighttime use	Yes	Yes	N/A
Indicated for single patient multiuse	Yes	Yes	N/A
Indicated for use in the patient's home	Yes	Yes	N/A
Target Population: Adults	Yes	Yes	N/A
Prescription device	Yes	Yes	N/A
Design			
Customized fit for each patient	Yes	Yes	N/A
Separate upper and lower tray pieces	Yes	Yes	N/A
Works by mandibular advancement	Yes	Yes	N/A
Advancement components are attached to the occlusal side of the device.	Yes	No	The SomnoDent G2 advancement components are attached to the buccal side. While these alignment features which prevent shifting from side to side have been changed to a simple rail system in line with the teeth, there are no additional forces introduced and no new questions of safety or effectiveness.
Can be adjusted or refit	Yes	Yes	N/A

	The Slide K203712	SomnoDent G2 – K121340	Evaluation of Differences
Lower jaw adjustment using supplied components	Yes	Yes	N/A
Permits patient to breathe through mouth	Yes	Yes	N/A
Upper and lower trays disengage for easy removal	Yes	Yes	N/A
Materials			
Splint	Yes	No, Trays constructed from a soft lining material adhered to a hard surface acrylic	The 3D trays are printed at Dental labs from materials approved to make dental splints. Use of 3D printed trays does not introduce any questions of safety or effectiveness.
Advancement mechanism constructed of biocompatible, medical grade polycarbonate	Yes	Yes	N/A

7. SUMMARY OF TECHNICAL CHARACTERISTICS OF DEVICE COMPARED TO PREDICATE DEVICE

7.1. The device and predicate device (K121340) are identical in the following ways:
- 7.1.1. Regulation name: Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
- 7.1.2. Regulation number: 21 CFR 872.5570
- 7.1.3. Regulatory Class: II

7.2. The predicate device claims product code LRK (anti-snoring), and the subject device claims LRK and LQZ (jaw repositioning). While the predicate device's submission does not reference product code LQZ, the mechanisms of action and intended use are in line with this code.

7.3. The predicate device has advancement components attached to the buccal side of the mouth, while the Slide has advancement components attached to the occlusal side of the mouth. While these alignment features which prevent shifting from side to side have been changed to a simple rail system in line with the teeth, there are no additional forces introduced and no new questions of safety or effectiveness. ***K203712.S003 Doc 010 046-0012 Device Mechanics Comparison*** includes a more in-depth discussion of these differences.

7.4. To demonstrate substantial equivalence, bench testing was conducted to assess the mechanical integrity of the subject device when subjected to forces expected in the patient's mouth during use. These results, summarized in ***Vol 018 Doc 001 Benchtop Performance Testing Overview***, indicated that the subject device performance is substantially equivalent to the predicate device, the SomnoDent G2, and it introduces no new questions of safety or effectiveness.

7.5. The subject device and predicate device have equivalent indications for use and technological characteristics, with the exception of the custom 3D printed tray, which does not introduce any questions of safety or effectiveness.

8. PERFORMANCE DATA

8.1. The following performance data were provided in support of the substantial

equivalence determination.

8.2. **Biocompatibility Testing**

8.2.1. Material biocompatibility established to be in compliance with **ISO 10993-1:2018**.

8.3. **Mechanical Testing**

8.3.1. Mechanical testing was performed to verify device functionality by assessing the maximum force the device can withstand to similar forces a patient's mouth will exhibit on the device. The mean peak force the device can withstand is 10 standard deviations above the acceptance criteria.

8.4. **Animal Study**

8.4.1. Animal performance testing was not required to demonstrate safety and effectiveness of the device.

8.5. **Clinical Studies**

8.5.1. Clinical testing was not required to demonstrate the safety and effectiveness of The Slide. Instead, substantial equivalence is based upon benchtop performance testing.

9. CONCLUSIONS

9.1. The subject device, The Slide, is substantially equivalent to the predicate device, the SomnoDent G2, and it introduces no new questions of safety or effectiveness.