Residential Home Sleep Services
Chris Gillette
Director of Dental Sleep Medicine
4602 Beckley Road
Battle Creek, Michigan 49015-7932

Re: K190353
Trade/Device Name: Bfit Sleep, Bfit Sleep with DentiTrac, Bfit Engage, Bfit Engage with DentiTrac
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: PLC, LRK
Dated: March 4, 2020
Received: March 4, 2020

Dear Chris Gillette:

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 Srivinas ‘Nandu’ Nandkumar, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K190353

Device Name
Bfit Sleep; Bfit Sleep with DentiTrac; Bfit Engage; Bfit Engage with DentiTrac

Indications for Use *(Describe)*

The BFit Intraoral Appliances are likely to reduce snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older.

Optionally, the DentiTrac Micro-Recorder may be incorporated into the Bfit device. The DentiTrac is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac System.

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

Applicant's Name	Residential Home Sleep Services 4602 Beckley Rd Battle Creek, MI 49015-7932 269.963.4118
Contact Person	Chris Gillette 4602 Beckley Rd Battle Creek, MI 49015-7932 269.963.4118 bfitsleep@gmail.com
Date Prepared	January 24 2019
Trade Name	Bfit Sleep; Bfit Sleep with DentiTrac; Bfit Engage; Bfit Engage with DentiTrac
Common or Usual Name	Oral appliance, Oral appliance with patient monitoring
Classification Name	Intraoral Devices for Snoring and Intraoral Devices for Snoring and Obstructive Sleep Apnea
Medical Specialty	Dental
Product Code	PLC, LRK
Device Class	II
Regulation Number	872.5570
Panel	Dental
Predicate Devices	Primary Predicate Device: Respire Pink Series with DentiTrac, K170692 Reference Device: ASD Elastic, K163580
Intended Use/Indications for Use	The BFit Intraoral Appliances are likely to reduce snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally, the DentiTrac Micro-Recorder may be incorporated into the Bfit device. The DentiTrac is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac System. Target Population: Adults 18 years and older. Environment of Use: Fitted by a clinician, used at home.

Device Description	The Bfit Intraoral Appliances are mandibular advancement devices which function by holding the jaw in a forward position during sleep (the principle of operation). The forward placement moves the tongue and pharyngeal tissue into a position to maintain an open airway, which allows the passage of more air per breath and helps in the treatment of snoring and mild to moderate Obstructive Sleep Apnea (OSA) - the intended effect. The Bfit Sleep and Bfit Engage use mild elastic pull during the different stages of sleep where muscle activity is lost. In addition, both models of the oral appliance may be provided to the patient with an embedded DentiTrac micro-recorder used to capture the patient's compliance to the prescribed oral appliance therapy. Each oral appliance is custom-fit to the patient. The Bfit is available in four possible configurations which differ only in connecting mechanism and whether a DentiTrac is installed: Bfit Sleep (elastics), Bfit Sleep with DentiTrac, Bfit Engage (tension springs), and Bfit Engage with DentiTrac.
Device Characteristics	The Bfit is provided non-sterile to the patient. It is custom-fit to the patient by the clinician. The materials used to manufacture the Bfit intraoral Appliances are commonly used dental materials; safety is demonstrated via biocompatibility testing.
Environment of Use	The Bfit is fitted by a clinician, used at home

Substantial Equivalence Comparison Table

Table 5-1:

Attribute	Bfit Intraoral Appliance (Subject)	Respire Pink Series with DentiTrac, K170692 (Primary Predicate)	ASD Elastic, K163580 (Reference Device)
Classification Status	Class II per regulations 872.5570	Same: Class II per regulations 872.5570	Class II per regulations 872.5570
Product Code	PLC, LRK	PLC, LRK	LRK
Indications for Use	The Bfit intraoral appliances are likely to reduce snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally, the DentiTrac Micro-Recorder may be incorporated into a Bfit. The Micro-Recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac System.	The Respire Pink Series intraoral appliances are intended to treat snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adult patients 18 years of age or older. Optionally, the DentiTrac micro-recorder may be incorporated into a Respire Pink Series device. The micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac system.	The ASD Oral Appliances are intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in individuals 18 years of age or older.
Target Population	Adults 18 years and older	Adults 18 years and older	Adults 18 years and older
Environment of Use	Fitted by a clinician, used at home	Fitted by a clinician, used at home	Fitted by a clinician, used at home
Principle of Operation	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate Obstructive Sleep Apnea (OSA)	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate Obstructive Sleep Apnea (OSA)	Once fitted to the patient, the device positions the lower jaw forward, preventing soft tissue of the throat from collapsing and obstructing the airway, therefore alleviating or reducing the symptoms of nighttime snoring and mild to moderate Obstructive Sleep Apnea (OSA)

Table 5-1:

Attribute	Bfit Intraoral Appliance (Subject)	Respire Pink Series with DentiTrac, K170692 (Primary Predicate)	ASD Elastic, K163580 (Reference Device)
Design	Mandibular repositioner having upper and lower polymer trays and elastic bands or stainless steel springs with stainless steel anchors.	Mandibular repositioner having upper and lower polymer trays with bilateral Herbst mechanisms.	Mandibular repositioner having upper and lower polymer trays and elastic bands or straps with stainless steel anchors.
Materials **Polymer Splint** **Connecting Mechanism**	 PMMA, EVA Latex-free Polymer or Stainless Steel	 Acrylic Stainless Steel	 PETG/TPU, EVA Latex-free Polymer
Sterility	Not sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Not sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.	Not sterile. Device is cleaned between uses by the patient following instructions provided by its manufacturer.
Micro-Recorder may be embedded into device	Yes	Yes	No

Non-clinical Performance Testing

The following non-clinical performance testing was provided by the material manufacturer to the FDA as part of this submission:

- Tensile strength (ASTM D-638)
- Flexural Strength (ASTM D-790)
- Flexural Modulus of Elasticity (ASTM D-790)
- Compressive Strength (ASTM D-695)
- Density (ASTM D-792)
- Melt Flow Rate (ASTM D-1238)
- Melting Point (ASTM D-3418)
- Vicat Softening Point (ASTM D-1525)

Bench Testing

- Bench testing to ensure durability of the appliance under normal wearing and cleaning conditions was also performed. The appliance passed all testing.

Biocompatibility Testing

A final, finished Bfit with an installed DentiTrac was tested for cytoxicity, sensitization and irritation as per ISO 10993. All tests resulted in a pass.

Test Performed	Device Description	Test Method/ Applicable Standard	Acceptance Criteria	Unexpected Results	Results
Cytoxicity MEM Elution Study# 1082899-S01	Bfit with DentiTrac	MEM Elution STP0032 Rev 10 ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytoxicity	no greater than 2 (Mild)	None	0=No reactivity Pass
Sensitization Kligman Maximization Test Study# 1082901-S01	Bfit with DentiTrac	Kligman Maximization Test ISO 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and delayed-type hypersensitivity	0 No reaction	None	0=No reaction Pass

Irritation Primary Oral (Buccal) Irritation Test-Acute Exposure Study# 1082900-S01	Bfit with DentiTrac	Primary Oral (Buccal) Irritation Test-Acute Exposure ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity	0 No irritation	None	0=No irritation Pass

Conclusion

In comparison to the predicate devices, the Bfit Intraoral Appliance has:

- the same intended use
- the same technological characteristics and so does not raise new questions of safety and effectiveness.

The Bfit is deemed substantially equivalent to the Respire Pink Series with DentiTrac, K170692 and ASD Elastic, K163580.