October 30, 2026

Aesyra SA
Marco Letizia
Epfl Innovation Park, Bat. C
Lausanne, 1015
Switzerland

Re: K260360
Trade/Device Name: AesyBite Active
Regulation Number: 21 CFR 882.5050
Regulation Name: Biofeedback Device
Regulatory Class: Class II
Product Code: HCC, MQC, PLC
Dated: October 2, 2026
Received: October 2, 2026

Dear Marco Letizia:

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 (the 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 available 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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download)

and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Office of Industry and Consumer Education (OICE) to ask a question about a specific regulatory topic. See the OICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-office-industry-and-consumer-education-oice) for more information or contact OICE by email (AskOICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation and
Physical Medicine Devices
OHT5: Office of Neurological and
Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K260360

Please provide the device trade name(s).

AesyBite Active

Please provide your Indications for Use below.

AesyBite Active is indicated to aid in the evaluation and management of sleep bruxism by monitoring and reducing bruxism activity during sleep, protect teeth from grinding, bruxism, and jaw clenching, protect restorations from injury due to bruxism or clenching.

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter

Aesyra SA
EPFL Innovation Park, Bat. C
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Switzerland
Phone: +41215050125
Contact: Marco Letizia, CEO
Email: marco.letiza@aesyra.com
Date: January, 30, 2026

Device Identification

Trade Name:	AesyBite Active
Classification Name:	Device, Biofeedback
Regulation Number:	882.5050
Product Code:	HCC
Subsequent Product Codes:	MQC, PLC
Device Class:	Class II
Classification Panel:	Neurology

Legally Marketed Predicate Devices

Primary Predicate Device:	GrindCare System	K163448
Secondary Predicate Device:	SmartGuard	K123161
Reference Device:	SomnoDent® with Micro-Recorder	K150369

Device description

AesyBite Active is a biofeedback system intended to reduce bruxism activity during sleep. The system comprises a boil-and-bite Oral Appliance embedded with sensors, designed to be worn by the user during sleep. A single-use, disposable Thermoforming Tray is provided to facilitate custom fitting of the Oral Appliance prior to first use. The system also includes a Charging Case and USB Cable, which are used for storage and recharging of the Oral Appliance between uses.

In addition to providing occlusal protection comparable to that of a conventional bruxism mouthguard, the Oral Appliance incorporates electronic components that detect and record sleep bruxism events and deliver targeted biofeedback stimuli via a miniature vibrating actuator. The stimulus, perceived by the user both tactilely and aurally, is intended to interrupt ongoing tooth grinding or clenching, thereby reducing bruxism activity.

Following use, recorded bruxism event data are transferred to the AesyBite Connect mobile application (“app”), which allows the user to review bruxism metrics and enter journal annotations.

Sleep bruxism is a masticatory muscle activity occurring during sleep, primarily characterized by the grinding and clenching of teeth. It is considered one of the most common sleep-related movement

disorders. The AesyBite Active device is intended for use in people over 18 years old who have been clinically diagnosed with sleep bruxism by a qualified healthcare professional.

The AesyBite Active medical device is composed of the following items:
- AesyBite Active Oral Appliance
- Thermoforming Tray
- AesyBite Connect mobile app
- AesyBite Charging Case
- USB Cable

Intended use

AesyBite Active is a biofeedback system intended to reduce bruxism activity during sleep.

Indications for use

AesyBite Active is indicated to aid in the evaluation and management of sleep bruxism by monitoring and reducing bruxism activity during sleep, protect teeth from grinding, bruxism, and jaw clenching, protect restorations from injury due to bruxism or clenching.

Substantial Equivalence Comparison Table

The following table summarizes the substantial equivalence of the subject device to the predicate and reference devices.

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
510 (k) number	K260360	K163448	K123161	K150369	/
Company Name	Aesyra SA	Sunstar Suisse S.A.	SmartGuard Inc	SomnoMed, Inc.	/
Device name	AesyBite Active	GrindCare System	SmartGuard	SomnoDent® with Micro-Recorder	/
Regulation Number	21 CFR 882.5050	21 CFR 882.5050	/	21 CFR 872.5570	Same as primary predicate
Regulation Description	Biofeedback device	Biofeedback device	Mouthguard, prescription	Intraoral devices for snoring and intraoral devices for snoring and obstructive sleep apnea.	Same as primary predicate
Product Code	HCC: Device, biofeedback	HCC: Device, Biofeedback	MQC: Mouthguard, Prescription	PLC: Sleep Appliances With Patient Monitoring	Same as primary predicate
Subsequent Product Codes	MQC: Mouthguard, Prescription PLC: Sleep Appliances With Patient Monitoring	KZM Diagnostic Electromyograph NUW Powered Muscle Stimulator	OBR: Mouthguard, Over-The-Counter	LQZ - device, jaw repositioning LRK - device, anti-snoring	/
Indications for use	AesyBite Active is indicated to aid in the evaluation and management of sleep bruxism by monitoring and reducing bruxism activity during sleep, protect teeth from grinding,	The GrindCare System is indicated to aid in the evaluation and management of sleep bruxism by reducing the temporalis muscle EMG activity during sleep.	Prescription (Rx): Protection of teeth grinding, bruxism, and jaw clenching. Protection of restorations from injury due to bruxism or clenching.	The SonnoDent intraoral devices are intended for the treatment of night time snoring and mild to moderate obstructive	The device integrates the indications for use of both predicates. It shares the primary therapeutic indication (reduction of bruxism

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
	bruxism, and jaw clenching, protect restorations from injury due to bruxism or clenching,		Relief of bruxism related headaches and pains. Short-term pain relief from muscle spasm due to occlusal interference; for the prevention of chronic tension and temporal mandibular joint (TMJ) syndrome that is caused by chronic jaw clenching of the mandibular and maxillary teeth by the temporalis muscles. Temporary treatment of Temporal mandibular Disorder (TMD) along with the relief of associated headaches and pains.	sleep apnea in patients 18 years of age or older. Optionally, if the DentiTrac micro-recorder is completely embedded into the SomnoDent® appliance, the micro-recorder is intended to measure patient compliance to oral appliance therapy in combination with the DentiTrac® System.	activity via biofeedback) with the Primary Predicate. It shares the preventive indications (protection of teeth/restorations) with the Secondary Predicate. The combination supports the duality of the device These indications for use are different from those of the reference device
Intended Use	AesyBite Active is a biofeedback system intended to reduce bruxism activity during sleep.	GrindCare System is a biofeedback system for reducing muscle activity during sleep	A dental mouthguard designed to protect teeth from the effects of bruxism (teeth grinding and clenching).	Oral appliance for the treatment of snoring and mild to moderate obstructive sleep apnea (OSA)	The device has the same biofeedback feature as the primary predicate and the same dental mouthguard design as the secondary predicate The Intended Use is different from that of the reference
Anatomical site	Oral cavity	Temple	Oral cavity	Oral cavity	Same as secondary predicate and reference
Reusable	Yes, single patient multiuse	No, single-use GelPad	Yes, single patient multiuse	Yes, single patient multiuse	Same as secondary predicate and reference

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
Patient Population	Adult patients 18 years and older	Not defined	Adult patients 18 years and older	Adult patients 18 years and older	Same as secondary predicate and reference
Use-Environment	Home	Home	Home	Home	Same as all predicates
Prescription	Prescription use	Prescription use	Prescription use (except for the following indications for use: protection against bruxism or night time teeth grinding, reducing damage to the teeth and noise associated with bruxing and/or grinding)	Prescription use	Same as primary predicate and reference. There are not exceptions.
Design	Custom fitted mouthguard (full arch)	Portable electromyography (EMG)	Custom fitted mouthguard (6-8 teeth)	Customized fit for each patient	Similar to secondary predicate. Specific design differences are addressed further below
Physical Characterization Material	Biocompatible material Thermoplastic Polymer (Ethylene vinyl acetate)	Biocompatible material	Biocompatible material Thermoplastic Polymer (Ethylene vinyl acetate)	Trays constructed from a soft lining material adhered to a hard surface acrylic. Advancement mechanism constructed of surgical grade stainless steel	Same as secondary predicate
Biocompatibility	ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, ISO 7405:2025	ISO 10993-5:2009, ISO 10993-10: 2010	No information provided	Biocompatibility, were assessed and tested	Same as primary predicate. However, the applicable clauses related to ISO 7405 are reasonable suitable also to secondary predicate device.

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
Sterility	Non-sterile	Non-sterile	Non-sterile	Non-sterile	Same as all predicates
Electrical safety	IEC 60601-1:2005+A1:2012, IEC 60601-1-11:2015+A1:2020	IEC 60601-1:2005+A1:2012, IEC 60601-1-2:2007, AM1:2012, CORR:2:2007, IEC 60601-1-6:2010	N/A	Electrical safety was assessed and tested	Same as primary predicate
Electromagnetic safety	IEC 60601-1-2:2014+A1:2020	IEC 60601-1-2:2007	N/A	EMC were assessed and tested	Same as primary predicate
Sensor Type	Capacitive sensors integrated in the Oral Appliance	A self-adherent and battery powered EMG sensor, to be placed on the skin of the temple	N/A	The DentiTrac Micro-Recorder is completely sealed under a layer of acrylic within the SomnoDent device.	Similar to reference
Power Source/ Charging	IEC 62133 compliant Lithium-ion rechargeable battery in the Oral Appliance. Inductive (wireless) link for charging the Oral Appliance battery.	IEC 62133 compliant Lithium-ion rechargeable battery in the Sensor Inductive (wireless) link for charging the Sensor battery.	N/A	Battery with a lifespan of two years	Same as primary predicate and reference
Communication	NFC communication for transferring data from the Oral Appliance to AesyBite Connect App	Infrared link for transferring data from Sensor to Docking Station. Bluetooth communication for transferring data from Docking Station to GrindCare App.	N/A	DentiTrac® data can be transferred to a cloud-based web application for reporting and tracking.	Similar to primary predicate and reference
Data storage	The Oral Appliance stores multiple nights of data.	Sensor stores only a single session of data. Docking Station stores up to 5 years of data.	N/A	During scheduled visits with the clinician, the data within the DentiTrac is uploaded to a web application for cloud-based	Similar to primary predicate and reference

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
				reporting and tracking using a DentiTrac Base Station at the clinician's office.	
Firmware	Yes	Yes	No	Yes	Same to primary predicate and reference
Internal memory	Yes	Yes	No	Yes	Same to primary predicate and reference
PCB with microprocessor	Yes	Yes	No	Yes	Same to primary predicate and reference
Viewing the Data	NFC for communication between the Oral Appliance and AesyBite Connect App on an Android device. Mobile app allows the user to review the grinding and clenching activity recorded by the Oral Appliance during sleep and to track its evolution over time.	Bluetooth type radio link for communication between Docking Station and GrindCare App on an iOS or Android device. There is no display on the device. Mobile App is used to view the data.	N/A	The data within the DentiTrac is uploaded to a web application for cloud-based reporting and tracking using a DentiTrac Base Station at the clinician's office.	Similar to primary predicate and reference
Biofeedback Setting	The biofeedback stimulus setting on the oral appliance, including enabling or disabling it and selecting the intensity level, is controlled by the user via the AesyBite Connect mobile app	The biofeedback stimulus setting on the Sensor, including enabling or disabling it and selecting the intensity level, is controlled by the user via the Sensor	N/A	N/A	Similar to primary predicate device
Biofeedback Stimulation	Vibratory stimulation	Electrical stimulation	No	No	Similar type of stimulation

	Subject Device	Primary Predicate	Secondary Predicate	Reference Device	Comments
Threshold	Automatically determined continuously based on a patient's background noise.	Automatically determined continuously based on background noise.	N/A	N/A	Same as primary predicate

Summary of the Technological Characteristics

The **Subject** device shares many fundamental design and technological characteristics with the predicates and the reference device:

- **Anatomical Site:** All devices, with the exception of the primary predicate, which is applied to the temple, are intended for use in the oral cavity. The **Subject** device is equivalent to the secondary predicate with respect to anatomical site of use. The intraoral anatomical site introduces well-characterized considerations, including contact with oral mucosa, potential effects on the airway, and electrical safety. These considerations do not represent new or different questions of safety or effectiveness, as they are well understood for intraoral dental devices and have been addressed through established risk controls. Specifically, biocompatibility of patient-contacting materials has been evaluated in accordance with ISO 10993 for mucosal contact, and electrical safety has been assessed in accordance with IEC 60601 requirements applicable to the device. Potential risks related to breathing discomfort or airflow restriction have been identified in the risk analysis and are mitigated through device design features and patient-specific fitting procedures intended to accommodate individual oral anatomy. In addition, clinical data support the use of the device within the oral cavity. Based on the above, the difference in anatomical site of use relative to the primary predicate does not raise new or different questions of safety or effectiveness, and substantial equivalence to the primary predicate is supported.
- **Patient Population and Environment of Use**: The **Subject** device and the predicates are intended for adult patients for home use and are available by prescription.
- **Materials and Biocompatibility**: AesyBite Active is manufactured from a biocompatible material (ethylene vinyl acetate, EVA), similar to SmartGuard and SomnoDent, and has been evaluated in accordance with ISO 10993-1:2018, ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021 and ISO 7405:2025. Compliance with these standards demonstrates that the **Subject** device has a material safety profile equivalent to that of the secondary predicate and reference devices.
- **Principle of Operation**: Like the primary predicate GrindCare System, AesyBite Active uses a biofeedback mechanism to reduce bruxism activity. Both devices automatically determine an intervention threshold based on the patient's background noise.
- **Power Source and Charging**: The **Subject** device incorporates a rechargeable lithium-ion battery within the oral appliance and utilizes a wireless charging interface. This feature is very similar to the reference device, which also incorporates a rechargeable lithium-ion battery within the oral appliance and is charged using a wireless base station.
- **Event Tracking**: Like the reference device, the **Subject** device is equipped with a micro-recorder designed to measure and control events through specific sensors incorporated into the oral appliance.
- **Electrical Safety and Firmware**: The **Subject** device complies with applicable electrical safety standards (IEC 60601-1:2005+A1:2012, IEC 60601-1-11:2015+A1:2020) and electromagnetic compatibility standards (IEC 60601-1-2:2014+A1:2020), consistent with the primary predicate and the reference device. The inclusion of firmware, a rechargeable battery, internal memory, and a microprocessor represents technological features that are also present in the primary predicate and the reference device, indicating a comparable level of technological complexity.

Discussion of Technological Differences

The main technological differences do not have a negative impact on the safety or effectiveness of the device; a more detailed analysis of the differences follows:

- **Sensor Type**: Although the AesyBite Active Oral Appliance incorporates capacitive force-sensing elements rather than the EMG-based sensor used in the GrindCare System, both technologies generate an equivalent monitoring output, the identification of sleep bruxism events. While the underlying technologies differ (mechanical force measurement versus electrical muscle activity measurement), this distinction does not affect the clinical interpretation of the recorded data. Published literature (Maoddi et al 2022) demonstrates that EMG-derived bruxism activity and force-sensing measurements obtained from an oral appliance are generally concordant, showing a strong correlation in the characterization of clenching and grinding events.
- **Biofeedback Stimulation:** The **Subject** device delivers vibratory stimulation within the oral cavity, whereas the primary predicate device delivers transcutaneous electrical stimulation via a gel pad positioned over the temporalis muscle. Despite differences in stimulation modality, both devices provide feedback to the user in response to detected activity, which is intended to reduce sleep bruxism activity. Vibratory stimulation is less invasive than transcutaneous electrical stimulation and does not introduce additional safety risks. Clinical data generated for the **Subject** device demonstrate a statistically significant reduction in bruxism activity, supporting comparable effectiveness to the electrical stimulation employed by the predicate device. Therefore, the difference in stimulation modality does not raise new or different questions of safety or effectiveness, and the **Subject** device is substantially equivalent to the predicate device.
- **Biofeedback Setting:** The **Subject** device, via the **AesyBite Connect mobile app,** allows the user to enable or disable the biofeedback stimulus and to select the intensity level. The primary predicate device allows the user to adjust the biofeedback stimulus directly by touching the Sensor. Although the user interfaces differ, both control methods achieve the same functional outcome: user-adjustable biofeedback stimulus settings. AesyBite Connect has been developed in accordance with IEC 62304 and has undergone comprehensive verification and validation activities, including requirements verification, software functional testing, cybersecurity assessment, and usability evaluation in accordance with IEC 62366-1. These activities confirm that the mobile app reliably and safely performs the intended control functions. Accordingly, the difference in biofeedback setting methods does not raise new or different questions of safety or effectiveness, and the **Subject** device can be considered substantially equivalent.
- **Device Design**: The **Subject** device utilizes a full-arch design, whereas the secondary predicate utilizes a partial-coverage design that covers only the anterior 6-8 teeth. Full-arch designs provide superior retention compared to partial-coverage designs, which may be at risk of displacement. Published literature (T. Bereznnicki et al 2018; and R. W. Wassell et al 2014) indicates that partial-coverage appliances have been associated with undesirable dental changes, such as posterior tooth extrusion and the development of anterior open bite, primarily due to the lack of posterior occlusal support. Consequently, full-arch designs are generally preferred for bruxism management, as they maintain proper posterior contact, protect the dentition and supporting structures, and reduce the risk of such adverse effects.

Although the devices fit within the oral cavity in a slightly different manner, the **Subject** device and the secondary predicate device share the same intended use, to protect teeth from the effects of bruxism by cushioning them and maintaining separation between opposing dentition. The **Subject** device additionally incorporates a biofeedback functionality. The electronic system used for event tracking in the **Subject** device is very similar to that of the reference device. This combination of features, consistent with those present in the reference device, does not introduce new or different risks.

Summary of Non-Clinical Performance Data

Bench testing

The following bench testing were provided in support of the substantial equivalence determination:

- Bruxism monitoring
- Oral appliance Dimensions
- Recharge interface
- Cell charging safety
- Cell discharging safety
- Cell duration
- Cell shelf life
- Biofeedback stimuli intensity
- Thermoforming tray dimensions
- Wear test
- Durability test
- Communication interface
- Oral appliance primary packaging
- Degrees of Protection Provided by Enclosures – IP68
- Transport test (ISTA3A SMALL)

All in-house and external bench performance tests were successfully completed. The results demonstrate that all components of the AesyBite Active System meet the applicable system requirements and comply with the relevant safety and performance standards. This confirms that the device performs as intended under the tested conditions

Biocompatibility testing

The biocompatibility assessment for AesyBite Active was conducted in line with the requirements of ISO 10993-1:2018 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”, ISO 14971:2019 “Medical devices — Application of risk management to medical devices” and US-FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" of September 8th 2023 (“FDA Guidance”).
After the physical and chemical assessment, the following tests have been performed:

- Cytotoxicity
- Sensitization
- Oral irritation
- Material mediated pyrogenicity

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and electromagnetic compatibility testing were conducted in accordance with IEC 60601-1:2005+A1:2012, IEC 60601-1-11:2015+A1:2020 and IEC 60601-1-2:2014+A1:2020.

Usability tests

The usability engineering process for AesyBite Active was conducted in accordance with the FDA guidance document *Applying Human Factors and Usability Engineering to Medical Devices: Guidance for Industry and Food and Drug Administration Staff* (2016, February 3), and IEC 62366-1-2015+A1-2020– *Medical Devices – Part 1: Application of Usability Engineering to Medical Devices*.

AesyBite Active has been found to be safe and effective for the intended users, uses, and use environments. The user interfaces of the device have been found to be adequately designed for the intended users, uses, and use environments.

A comprehensive task analysis and risk assessment were performed to identify any user interactions that could result in serious harm if performed incorrectly. The results of this assessment demonstrated that the device does not involve any user tasks classified as critical—defined as tasks which, if performed incorrectly or not performed at all, would or could cause serious harm to the patient or user, where harm is defined to include compromised medical care.

To determine whether any tasks met this criterion, the following factors were evaluated:

- The severity of harm that could result from task errors,
- The likelihood of such errors occurring.

The following user interactions with AesyBite Active were reviewed:

- Configuring the biofeedback settings in the mobile app,
- Recharging the oral appliance in the Charging Case,
- Reviewing bruxism monitoring data in the mobile app
- Synchronization of AesyBite Active Oral Appliance with the mobile app

All tasks were classified as low risk and do not present a realistic potential for serious injury, even if performed incorrectly.

To validate these assumptions and support risk characterization a series of formative usability evaluations were conducted.

During these sessions all participants were able to complete the tasks independently after reviewing the instructions for use.

No new use-related hazards were identified during formative testing, and users expressed confidence in performing all necessary tasks independently.

Given the low-risk nature of the product, it was concluded that:

- No tasks meet the criteria for classification as critical under the FDA's definition,
- Residual use-related risks are low and acceptable, requiring no additional risk controls beyond those already implemented in the current design and labelling.

This conclusion supports the determination that a summative usability validation study is not warranted under the applicable regulatory requirements.

Based on the results of this usability engineering process, it is concluded that:

- AesyBite Active can be considered safe and effective for the intended users, uses, and use environments.
- The device's user interfaces are appropriate for the intended use, users, and environments.

- There are no critical tasks, as none of the user interactions present a risk of serious harm.

Clinical Performance Data

The clinical investigation titled *"Efficacy of AesyBite Active in Reducing Sleep Bruxism Activity"* was conducted to evaluate the clinical performance and safety of AesyBite Active when used according to its intended use to reduce bruxism activity during sleep. The study was designed and conducted in accordance with ISO 14155:2020, applicable regulatory requirements, and ethical principles.

The study was a three-period parallel group open-label randomized before and after study in which subjects were randomized after completing a 1-week adaptation phase into early or delayed stimulation arms. Biofeedback was activated after a 1-week baseline phase for participants in the early stimulation arm and maintained for two weeks. For subjects in the delayed stimulation arm biofeedback was activated after a 2-week baseline phase and maintained for one week.

study was a single center study conducted outside of United States, at San Gerardo Hospital in Monza (Italy)

The primary objective was to evaluate the efficacy of AesyBite Active in reducing sleep bruxism activity (endpoint total sleep bruxism duration per hour [TDPH, sec/hour]) by at least 60% in the stimulation phase compared with baseline with a 10% non-inferiority margin.

The incidence of adverse events, serious adverse events, and device deficiencies was evaluated to assess safety.

A total of 59 volunteers were screened for eligibility at the study site in Monza, of which 43 were eligible and enrolled in the adaptation phase. 9 participants showed no bruxism activity. Bruxism activity was considered as absent when a bruxism index lower than 1 was recorded. Participants with a bruxism index lower than 1 after one week of adaptation were excluded from the study. 3 subjects did not adhere to the study procedures. Participants who unintentionally removed the oral appliance during the night, or who slept less than 4 hours per night for more than 3 nights, were excluded from the study. 5 participants declined to continue.

Finally, 26 were randomized (13 allocated to early and 13 to delayed stimulation) and provided valid sets of bruxism sleep records during the baseline and stimulation phases.

AesyBite Active demonstrated a significant reduction of the sleep bruxism activity. The reduction in the primary endpoint TDPH was 60.6% (55.8% to 64.9%) after adjustment for within-subject correlation (P-value < 0.001 to reject the null hypothesis that the reduction was inferior to 50%).

No adverse events were reported during the clinical investigation. Two device deficiencies were reported, resulting in replacement of the device, with no impact on patient safety.

The results of this clinical investigation support the conclusion that the investigational device performs as intended within the defined intended use.

Statement of Substantial Equivalence

Nonclinical and clinical testing demonstrate that the device is as safe and effective as, and performs as well as, the predicate devices. The indications for use, patient population, environment of use, principle of operation, and performance of the subject device are substantially equivalent to those of the predicate devices and do not raise new questions of safety or effectiveness.

Any differences in design or technological characteristics are well understood, and the data provided in this submission support the safety and effectiveness of the subject device. The clinical study of the subject

device demonstrated a statistically significant reduction in all bruxism indices with no reported adverse effects, showing effectiveness comparable to that of the primary predicate. The comparable magnitude of effect provides strong evidence of performance equivalence, supporting the safety and effectiveness of the subject device for its intended use in reducing sleep bruxism, despite differing mechanisms of action.

The reference device further demonstrates that active technological features, including a battery within the intraoral environment, have been legally marketed with established safety and reliability. Based on comparison to the predicate devices, the technological differences do not raise different questions of safety and effectiveness; therefore, the subject device can be considered substantially equivalent.