February 22, 2023

NeuroVice, LLC
% John Hayes
Manager, Product Development
Gilero, LLC
635 Davis Drive, Suite 100
Morrisville, North Carolina 27560

Re: K221469
Trade/Device Name: PATI (Protector Against Tongue Injury)
Regulation Number: 21 CFR 882.5070
Regulation Name: Bite block
Regulatory Class: Class II
Product Code: JXL
Dated: January 23, 2023
Received: January 23, 2023

Dear John Hayes:

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,

Robert Kang -S

for Pamela Scott
Assistant Director
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

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)*
K221469

Device Name
PATI (Protector Against Tongue Injury)

Indications for Use *(Describe)*
The PATI device is a single-use (disposable) oral protector for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa. The PATI is indicated for use with any individual aged 12 or older who suffers from seizures and can be used in a clinical or non-clinical environment.

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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5.0 510k Summary

Company Name: NeuroVice, LLC
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Company Phone: +1 (919) 260-5023

Official Contact: Amanda Schaffers
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E-mail: aschaffers@gilero.com

Submission Date: May 19, 2022

Device Identification:

Trade Name:	Protector Against Tongue Injury (PATI)
Device Class:	2
Regulation Number:	21 CFR 882.5070
Regulation Name:	Block. Bite
Product Code:	JXL
Review Panel:	Neurology

Predicate Device:

Manufacturer:	Surgovations, LLC
Trade Name:	SurgeoBite
510(k):	K172978

Device Description:
The Protector Against Tongue Injury (PATI) device is a symptom-management, oral device technology that helps to protect against oral injury during seizures, while also allowing fluids to naturally drain or be suctioned. The device will be administered by the patient, an assistant, or medical personnel, (such as hospital staff, EEG technicians, or first responders, including EMTs and paramedics), prior to full onset of a seizure. The device is single use and disposable.

Indications for Use:
The PATI device is a single-use (disposable) oral protector for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa. The PATI is indicated for use with any individual aged 12 or older who suffers from seizures and can be used in a clinical or non-clinical environment.

Technological Characteristics and Substantial Equivalence:
The following chart presents an overview of comparisons between the subject device (PATI) and the predicate device (Surgovations LLC Surgeobite):

Device Attribute	SUBJECT: [NeuroVice] PATI	PREDICATE: [Surgovations] SurgeoBite (K172978)
Device Class	II	II
Device Classification Name	Block, Bite	Block, Bite
Regulation Number	882.5070	882.5070
Product Code	JXL	JXL
Intended Use	The PATI device is a single-use (disposable) oral protector for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa.	The SurgeoBite device is a single-use (disposable) oral protector for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa.
Indications for Use	The PATI device is a single-use (disposable) oral protector for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa. The PATI is indicated for use with any individual aged 12 or older who suffers from seizures and can be used in a clinical or non-clinical environment.	The SurgeoBite device is single-use (disposable) oral protector for use during seizures induced by electroconvulsive therapy, spontaneous seizures, neuromonitoring stimulation, and any circumstances requiring protection of the teeth, lips, tongue, and buccal mucosa.
Materials	Medical grade thermoplastic elastomer (TPE): Versalloy™ HC 9210-55N Thermoplastic Elastomer with TPV Sky Blue 278C Colorant	Medical grade silicone rubber
Principles of Operation	The device is positioned into the mouth and provides a biting surface between the teeth making sure that the tongue and cheeks are not between the biting surfaces. The device protects the teeth, lips, tongue, and buccal mucosa.	The device is positioned into the mouth and provides a biting surface between the teeth making sure that the tongue and cheeks are not between the biting surfaces. The device protects the teeth, lips, tongue, and buccal mucosa.
Technology and Design	General design: one piece, single-use bite block Profile: Mouth guard walls that reside in the space between the buccal tissues and the teeth. Bite pads to cushion teeth during biting or clenching. Opening in the front of the device for salivary drainage. The PATI is not designed for feature compatibility with endotracheal tubes. The subject device additionally features a handle to help facilitate device placement while allowing the fingers of the individual placing the device to remain outside of the mouth during placement for additional protection and safety of the user.	General design: one piece, single-use bite block Profile: Mouth guard walls that reside in the space between the buccal tissues and the teeth. Bite pads to cushion teeth during biting or clenching. Opening in the front of the device for salivary drainage. Designed for feature compatibility with endotracheal tubes.
Biocompatibility	The subject device has been evaluated through biocompatibility testing (ISO 10993 Cytotoxicity, Sensitization, and Irritation) to ensure device safety for patient contact in accordance with the indications for use.	The predicate device material as manufactured is compliant under ISO 10993-1 for Cytotoxicity, Sensitization, and Irritation.
Sterilization	Non-sterile	Non-sterile

Device Attribute	SUBJECT: [NeuroVice] PATI	PREDICATE: [Surgovations] SurgeoBite (K172978)
Prescription	RxOnly	RxOnly
Reuse	Single use	Single use

Substantial Equivalence:
The PATI is substantially equivalent to the predicate: Surgovations LLC Surgeobite.

Both devices are oral protectors for use during spontaneous seizures and any circumstances requiring the protection of the teeth, lips, tongue, and buccal mucosa. Both devices are single-use (disposable) and are non-sterile. The devices are very similar in their design and principles of operation in that they both feature mouth guard walls that reside in the space between the buccal tissues and the teeth, bite pads to cushion teeth during biting or clenching, and an opening in the front of the device for salivary drainage.

While the subject PATI has different indications for use compared to the available information for the predicate device, the devices have the same intended use.

The differences in the indications for use of the PATI as compared to the predicate device include:

1. The use circumstances indicated for the subject PATI device are a subset of the predicate device, as the subject device is not indicated for use during seizures induced by electroconvulsive therapy or neuromonitoring stimulation, where the predicate Surgeobite is.
2. Clarification of the patient population to include adolescents and adults
3. Clarification of the permissible use environment to include clinical and non-clinical environments

The use considerations of the adolescent population of (2) and the lay users associated with the non-clinical use of the device of (3) above have been adequately addressed through design, risk analysis, product labeling, and the Summative Human Factors Testing.

Finally, the subject PATI and the predicate SurgeoBite utilize different materials for their constructions, but the subject device was appropriately evaluated for biological safety consistent with its patient contact and duration of use.

Discussion of Non-clinical Tests:
The following non-clinical tests were conducted to demonstrate substantial equivalence to the predicate device.

Biocompatibility:
The PATI, like the predicate device, was evaluated for biocompatibility appropriate to the contact characterization (type and duration), in accordance with the requirements of ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and the FDA Guidance for Industry - Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". Specific testing included:

- Cytotoxicity

- Sensitization
- Irritation or Intracutaneous Reactivity

Performance Testing:
The following performance data were provided in support of this Premarket Notification:

- Simulated Use Bite Force and Displacement Testing

Human Factors Testing
Summative Human Factors testing was performed using 30 users across adolescent and adult user groups to demonstrate that the subject device promotes safe and effective use across all user groups.

Conclusion
The information in this submission supports the safety and efficacy of the subject device for its intended use and demonstrates substantial equivalence with the predicate device. The PATI's differences in material, technology and operation from the predicate device do not raise new questions about safety and effectiveness.