December 22, 2017

Surgovations LLC
% Julie Stephens
President/Consultant
Regulatory Resources Group, Inc.
111 Laurel Ridge Dr
Alpharetta, Georgia 30004

Re: K172978
Trade/Device Name: SurgeoBite
Regulation Number: 21 CFR 882.5070
Regulation Name: Bite Block
Regulatory Class: Class II
Product Code: JXL
Dated: September 27, 2017
Received: September 27, 2017

Dear Julie Stephens:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2017.12.22 08:39:24 -05'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K172978

Device Name
SurgeoBite®

Indications for Use *(Describe)*
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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

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

Submitted By: Surgovations LLC
110 Fairway Run
Forsyth, GA 31029
Phone: (478) 254-1707

Contact Person: Julie Stephens - Regulatory Resources Group, Inc.
Regulatory Consultant
Phone: (678) 513-0693

Date Submitted: September 27, 2017

Device Name and Classification:

Trade/Proprietary Name:	SurgeoBite ®
Common Name:	Bite Block
Classification Name:	Bite Block
Regulation:	21 CFR 882.5070
Class:	II
Product Code:	JXL

Legally Marketed Predicate Device:

Ventil-A - Somatics, LLC - 510(k) # K992269

Device Description:

The SurgeoBite is designed to be an easy to use and safe device for use in the patient's mouth. The shape of the device allows for easy positioning into the mouth and provides a biting surface between the teeth making sure that the tongue and cheeks are not between the biting surfaces. During seizures induced by electroconvulsive therapy, neuromonitoring stimulation, spontaneous seizures, and circumstances requiring protection, the jaw muscles can contract and cause potential damage to the teeth and mouth tissues. By placing the oral protector in the patient's mouth, it will provide protection of the teeth, lips, tongue, and buccal mucosa. The SurgeoBite is sold nonsterile, single use, and is discarded after use.

Indications for Use:

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.

510(k) SUMMARY

Similarities and Differences to the Predicate Devices:

Similarities

The SurgeoBite (proposed device) has the same basic technology characteristics as they are both one piece, single use bite blocks and the indications for use are the same as the Ventil-A (predicate device).

Differences

The SurgeoBite (proposed device) uses a different profile and does not use the same material as the Ventil-A (predicate device). The material used by the SurgeoBite is a medical grade silicone rubber. The material used by the Ventil-A is a closed-cell foam. The addition of neuromonitoring stimulation into the indications for use for the SurgeoBite delineates a current usage that meets the definition of "circumstance requiring protection of the teeth, lips, tongue, and buccal mucosa".

Summary of Testing:

The biocompatibility risk assessment was completed as directed by FDA guidance under ISO 10993-1 biocompatibility requirements. The silicone rubber material as manufactured is compliant under ISO 10993-1 for Cytotoxicity, Sensitization, and Irritation. Performance testing completed for SurgeoBite included Bite Force Testing, Displacement Testing, and Testing with Endotracheal Tubes.

Substantial Equivalence Conclusions:

All of the testing results for SurgeoBite passed within the acceptance parameters and demonstrated a safe and reliable device for providing protection of the teeth, lips, tongue, and buccal mucosa. The completion of the testing demonstrates that the SurgeoBite has the same principles of operation, indications for use, and technological characteristics as the predicate device.