June 4, 2021

MECTA Corporation
Adrian Kettering
Vice President
19799 SW 95th Avenue
Suite B
Tualatin, Oregon 97062

Re: K201309
Trade/Device Name: ECT Cotton Bite Block- size Large, ECT Cotton Bite Block -size Medium
Regulation Number: 21 CFR 882.5070
Regulation Name: Bite Block
Regulatory Class: Class II
Product Code: JXL
Dated: March 6, 2021
Received: March 8, 2021

Dear Adrian Kettering:

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 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)*
K201309

Device Name
ECT Cotton Bite Block

Indications for Use *(Describe)*
The ECT Cotton Bite Block is a single-use (disposable) oral protector for use during seizures induced by electroconvulsive therapy (ECT), to protect the patient's lips, teeth and tongue. It is placed between the back molars, with the tongue medial, and one side of the bite block sticking out of the patient's mouth to keep the mouth open.

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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510K Summary

Submitter's Information

Name of Sponsor: MECTA Corporation
Address: 19799 SW 95th Ave, Suite B, Tualatin, OR 97062
Contact Name: Adrian Kettering
Telephone: 503-612-6780
Fax: 503-612-6542
Email: akettering@mectacorp.com

Trade Name, Common Name, Classification [21 CFR807.92 (a) (2)]

Trade Name/Model: MECTA ECT Cotton Bite Block
Classification Name: Neurological Therapeutic Devices, Bite Block
Regulation Number: 882.5070
Product Code: JXL
Classification Panel: Neurological Devices
Device Class: II

Identification of Predicate Device

The identified predicate within this submission is the Somatics, Inc. Ventil-A Oral Protector that was cleared by FDA through 510K No. K992269 (Decision date: October 25, 1999).

Description of Device

During the passage of the electrical stimulus during ECT, despite the fact that the patient has been given a systemic muscle relaxant, the masseter muscles contract forcefully, necessitating the use of a bite block or mouth guard. The ECT Cotton Bite Block is intended for single-use only, and is placed between a patient's back molars in order to protect the teeth and tongue during an electroconvulsive therapy (ECT) treatment. Patients who are mentally ill commonly have poor oral hygiene. The placement of the bite block, only on one side of the mouth, allows for any damaged or compromised molars on the opposite side of the mouth to be free from compression. In addition, incisors avoid the risk of being damaged during compression, and the ¾" thick soft cotton provides necessary cushioning for the remaining teeth that are biting down on the cotton roll. One end of the bite block remains outside of the mouth, propping the mouth open for oxygen to be administered, and to ensure that the bite block is staying in place.

Material: The ECT Cotton Bite Block is made of 100% purified medical grade cotton, and is a cylindrical shaped dense cotton roll wrapped in cotton silky yarns.

Sizes: There are two sizes, and size used is determined by the patient's mouth size. The large size is ¾ inch diameter and 4 inches long, and the medium is ¾ inch diameter and 2 ¾ inches long.

Environment: Electroconvulsive Therapy is administered in a hospital operating room or ECT Suite.

Intended Use
The ECT Cotton Bite Block is a single-use (disposable) oral protector for use during seizures induced by electroconvulsive therapy (ECT), to protect the patient's lips, teeth and tongue. It is placed between the back molars, with the tongue medial, and one side of the bite block sticking out of the patient's mouth to keep the mouth open.

Comparison of Technological Characteristics
The ECT Cotton Bite Block is substantially equivalent to its predicate device in that both bite blocks protect the compression of the back molars when the masseter muscles contract during electroconvulsive therapy, both allow the airway to remain open, and both are single-use. However, the ECT Cotton Bite Block differs in the material used and the shape.

Substantial Equivalence

Comparison Item	Proposed Device: ECT Cotton Bite Block	Predicate Device: Ventil-A Oral Protector
Shape	A cylindrical shape that offers two sizes, depending upon the size of the patient's mouth. For both, the diameter is ¾", and the two lengths are 2.75" for medium or 4" for large. This shape allows minimal teeth to be affected by compression, especially the more delicate and vulnerable front incisor teeth, and any damaged or compromised molars on one side of the mouth.	A triangular shape with rounded edges and a punched hole in the middle. Thickness is 3/8". Only available in one size.
Material	A one-piece bite block made of 100% Cotton roll bound by Cotton Silky Threads.	A one-piece bite block made of closed-cell foam construction.

Performance and Biocompatibility Testing
Compression testing was conducted on the ECT Cotton Bite Block, using the maximum human bite force of 600 N, and the ECT Cotton Bite Block was found to compress enough to cushion the teeth, but did not compress under the lower limit of 7 mm compression.

Extensive biocompatibility testing was conducted at WuXi Laboratories, including sensitization, intracutaneous irritation and cytotoxicity. The MECTA ECT Cotton bite block passed all of these tests in a very straightforward manner with a score of all zeros.

Substantial Equivalence Conclusions
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification, MECTA Corporation concludes that:

- The intended use of the MECTA ECT Cotton Bite Block is the same as the predicate device.

- The ECT Cotton Bite Block protects the ECT patient's mouth, with differences in the shape and material in order to protect compromised teeth, which can be common for patients who are mentally ill.