May 19, 2023

Entac Medical Inc.
% Adam Harris
Senior Director, Regulatory and Strategic Development
Target Health LLC
450 Commerce Boulevard
Carlstadt, NJ 07072

Re: K230769
Trade/Device Name: PrevisEA Device
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: March 17, 2023
Received: March 21, 2023

Dear Adam Harris:

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,

Shanil P. Haugen -S

Shanil P. Haugen, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity and Transplant Devices
OHT3: Office of GastroRenal, ObGyn, General Hospital and Urology 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)*
K230769

Device Name
PrevisEA Device

Indications for Use *(Describe)*
PrevisEA is a compact, non-invasive device placed on the abdomen to capture the digestive sounds of patients. PrevisEA displays information which assists physicians in assessing the digestive health of patients. This device is for prescription use only and should be used under the direction of a licensed healthcare practitioner. The PrevisEA device has not been tested for and it is not intended for pediatric use.

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.

5. 510(k) Summary

5.1 Applicant

Entac Medical Inc.
680 Oakleaf Office Lane, Suite 201
Memphis, TN 38117

5.2 Contact Person

Adam Harris, MM, RAC
Senior Director, Regulatory and Strategic Development
450 Commerce Boulevard
Carlstadt, NJ 07072
Telephone: 646-479-2437
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5.3 Date of Summary: January 27, 2023

Device Proprietary Name	PrevisEA™ Device		
Common/Usual Name	Electronic Stethoscope		
Classification Names / Numbers and Code	**21 CFR**	**Classification Name**	**Code**
	870.1875	Electronic Stethoscope	DQD
Regulatory Class	2		
Prescription Status	Prescription Device		
Classification Panel	Gastroenterology		
Predicate Device	K211068	PrevisEA™ Device	
Description of Device	PrevisEA is a non-invasive, self-contained, medical device with a proprietary algorithm used to assess the digestive health of patients. The device includes a stethoscope diaphragm, sound chamber, embedded microphone and CPU, as well as a display screen and buttons. The PrevisEA device is a convenient, single-use, disposable unit, which attaches to the abdomen of the patient via an adhesive wafer on the back of the device. The PrevisEA is a single-use, disposable unit, which avoids the need for cleaning and disinfection. The PrevisEA requires no cable connections for operation of the device. Integration of the above components allow auscultation and digital capture of digestive sounds, such as MH4. Messages are transmitted to the easy-to-read display screen on the front of the device. The PrevisEA detects the acoustic biomarker MH4 and quantifies the number of MH4 detections over a 4-minute interval, which it compares to a predefined threshold to determine the presence of abnormal digestive health in patients following major abdominal surgery, such as gastrointestinal impairment (GII).		
Indications for Use/Intended Use	PrevisEA is a compact, non-invasive device placed on the abdomen to capture the digestive sounds of patients. PrevisEA displays information which assists physicians in assessing the digestive health of patients. This device is for prescription use only and should be used under the direction of a licensed healthcare practitioner. The PrevisEA device has not been tested for and it is not intended for pediatric use.		

Table 1: Substantial Equivalence Comparison Table

	Subject Device	Predicate Device
	Entac PrevisEA Device	**Entac PrevisEA Device**
510(k) Number	TBA	K211068
Product Code	DQD	DQD
Regulation	21 CFR 870.1875 Stethoscope	21 CFR 870.1875 Stethoscope
Intended Use	PrevisEA is a compact, non-invasive device placed on the abdomen to capture the digestive sounds of patients. PrevisEA displays information which assists physicians in assessing the digestive health of patients. This device is for prescription use only and should be used under the direction of a licensed healthcare practitioner. The PrevisEA device has not been tested for and it is not intended for pediatric use.	PrevisEA is a compact, non-invasive device placed on the abdomen to capture the digestive sounds of patients. PrevisEA displays information which assists physicians in assessing the digestive health of patients. This device is for prescription use only and should be used under the direction of a licensed healthcare practitioner. The PrevisEA device has not been tested for and it is not intended for pediatric use.
Device Description	PrevisEA is a non-invasive, self-contained, medical device with a proprietary algorithm used to assess the digestive health of patients. The device includes a stethoscope diaphragm, sound chamber, embedded microphone and CPU, as well as a display screen and buttons. The PrevisEA device is a convenient, single-use, disposable unit, which attaches to the abdomen of the patient via an adhesive wafer on the back of the device. The PrevisEA is a single-use, disposable unit, which avoids the need for cleaning and disinfection. The PrevisEA requires no cable connections for operation of the device. Integration of the above components allow auscultation and digital capture of digestive sounds, such as MH4. Messages are transmitted to the easy-to-read display screen on the front of the device. The PrevisEA detects the acoustic biomarker MH4 and quantifies the number of MH4 detections over a 4-minute interval, which it compares to a predefined threshold to determine the presence of abnormal digestive health in patients following major abdominal surgery, such as gastrointestinal impairment (GII).	PrevisEA is a non-invasive, self-contained, medical device with a proprietary algorithm used to assess the digestive health of patients. The device includes a stethoscope diaphragm, sound chamber, embedded microphone and CPU, as well as a display screen and buttons. The PrevisEA device is a convenient, single-use, disposable unit, which attaches to the abdomen of the patient via an adhesive wafer on the back of the device. The PrevisEA is a single-use, disposable unit, which avoids the need for cleaning and disinfection. The PrevisEA requires no cable connections for operation of the device. Integration of the above components allow auscultation and digital capture of digestive sounds, such as MH4. Messages are transmitted to the easy-to-read display screen on the front of the device. The PrevisEA detects the acoustic biomarker MH4 and quantifies the number of MH4 detections over a 4-minute interval, which it compares to a predefined threshold to determine the presence of abnormal digestive health in patients following intestinal surgery, such as gastrointestinal impairment (GII).

Table 2: Summary of Technological Characteristics Compared to the Predicate Device

Technological Characteristic		Comparison
Number of Sensors	1 – self contained	Same
Sensor size (mm) Active Area	3 inches	Same
Algorithm	Algorithm technology to specifically evaluate gastrointestinal auditory biomarker MH4	Same
Sensor Technology	Standard electrical microphone	Same
System Technology	Sensor data signal processing and computing	Same
Power Supply	Lithium-Ion Battery	Same
Software	Processes audio signals for display and presentation to the user.	Same
Abdomen placement	Placed in any quadrant of the patient abdomen.	Same

5.4 Purpose of the Submission

The purpose of this submission is for a change to the wording in the description of the PrevisEA Device.

5.5 Testing Summary

No new testing was performed for this submission. Biocompatibility, electrical safety, shelf-life, and clinical testing were submitted for the original application for K211068.

5.6 Substantial Equivalence Conclusion

For this submission, the Subject and Predicate devices are the same. The Subject and Predicate devices have the same intended use/indications for Use, and there are no differences in technological characteristics between the Subject and Predicate devices.

The sponsor has provided a systematic review of published literature supporting the proposed labeling change. The information provided in this submission demonstrates that the proposed change does not raise new questions of safety and efficacy. It is the conclusion of the sponsor that the subject device is substantially equivalent to the Predicate device.