August 4, 2021

Entac Medical Inc.
% Adam Harris
Director, Regulatory Affairs
Target Health LLC
261 Madison Avenue, 24th Floor
New York, NY 10016

Re: K211068
Trade/Device Name: PrevisEA Device
Regulation Number: 21 CFR 870.1875
Regulation Name: Stethoscope
Regulatory Class: Class II
Product Code: DQD
Dated: May 5, 2021
Received: May 7, 2021

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,

for
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)*
K211068

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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
Director, Regulatory Affairs
Target Health LLC
261 Madison Avenue, 24th Floor
New York, NY 10016
Telephone: (646) 218-2009
aharris@targethealth.com

Date of Summary: July 8, 2021

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	K150782	GI Logic AbStats® Gateway	
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 intestinal 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	**GI Logic Abstats Gateway**	**Comparison**
510(k) Number	K211068	K150782	Same
Product Code	DQD	DQD	Same
Regulation	21 CFR 870.1875 Stethoscope	21 CFR 870.1875 Stethoscope	Same
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 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.	The AbStats Gateway is a compact device with integrated sensor interfaces and embedded computing system (stethoscope) that in conjunction with external sensors constitutes the AbStats system. The AbStats system external sensors are placed on the abdomen and identify the vibratory signals associated with digestive processes. This device should be used under the direction of a licensed healthcare practitioner when it is required to determine this patient digestive state. The device has not been tested for and it is not intended for pediatric use.	Substantially equivalent
Number of Sensors	1 – self contained	2 – external	Different number and location but substantially equivalent functionality
Sensor Size (mm) Active Area	3 inches	30 mm x 20 mm 400 mm2	Different size but substantially equivalent functionality

Table 1: Substantial Equivalence Comparison Table (Continued)

	Subject Device	Reference Device	Comparison
	Entac PrevisEA Device	**GI Logic Abstats Gateway**	
Algorithm	The PrevisEA utilizes algorithm technology to specifically evaluate gastrointestinal auditory biomarker MH4	The Abstats Gateway utilizes algorithm technology to recognize and classify gastrointestinal signals	Different but Subject and Reference devices have similar functionality
Sensor Technology	Standard Electrical Microphone	Standard Electrical Microphone	Substantially equivalent
System Technology	Sensor data signal processing and computing	Sensor data signal processing and computing	Substantially equivalent
Interface to PC	None required (no PC Interface)	None required (no PC Interface)	Substantially equivalent
Power Supply	Lithium-Ion Battery	5V USB Power Source	Different but substantially equivalent functionality
Sensor Cable Length (m)	N/A – none required	2.0 m	Different but substantially equivalent functionality
IEC6060 1-1:2005 3rd Edition Medical Electrical Equipment Part 1: General Requirement or Safety	Conforms	Conforms	Substantially equivalent
EN60601-1-2, 2007/03, EMC Requirements for Safety, 2. Collateral Standard – Electromagnetic Compatibility Requirements and Tests	Conforms	Conforms	Substantially Equivalent
Immunity Requirements for Medical Electrical Equipment Part 1: General	Conforms	Conforms	Substantially Equivalent

Table 1: Substantial Equivalence Comparison Table (Continued)

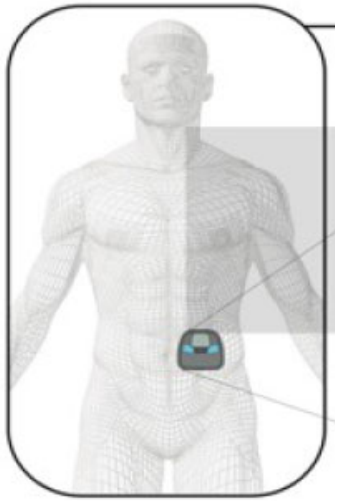
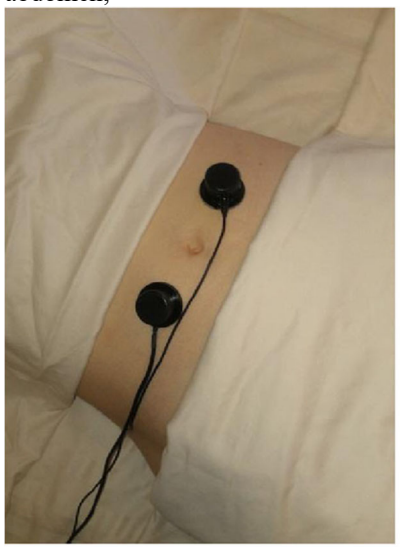
	Subject Device	Reference Device	Comparison
	Entac PrevisEA Device	**GI Logic Abstats Gateway**	
Biocompatibility	Testing demonstrated all patient contacting materials for the PrevisEA device to be safe and biocompatible	No biocompatibility testing performed as the only patient contact consists of commercially available dermal adhesive dressings	Substantially Equivalent
Software	The PrevisEA software processes audio signals for display and presentation to the user.	The AbStats software processes audio signals for display and presentation to the user.	Substantially Equivalent
Auscultation Performance Tests: Bench Testing	Passed/Conforms	Passed/Conforms	Substantially Equivalent
Clinical performance validation	Listens for the MH4 acoustic biomarker	Listens for acoustic event rates to determine an intestinal motility	Different mechanism/parameter of assessment but does not raise new issues of safety and efficacy.
Abdomen Placement	The PrevisEA is placed in any quadrant of the patient's abdomen. 	AbStats external sensors placed on the abdomen, 	Substantially Equivalent

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

Characteristics	PrevisEA	Abstats Gateway
Electronic Stethoscope	Yes	Yes
Non-invasive system	Yes	Yes
Attach to abdomen	Yes	Yes
Auscultation device	Yes	Yes
Assess digestion specifically	Yes	Yes
Algorithm technology	Yes	Yes
Self-contained sensors	Yes	No
Batter powered	Yes	No

5.3 Biocompatibility Testing

Biocompatibility tests were conducted with the PrevisEA Device according to *ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process*. These studies demonstrated the PrevisEA Device is biocompatible.

5.4 Electrical Safety and Electromagnetic Compatibility (EMC)

Electrical product safety, electromagnetic compatibility, and battery safety testing were performed for the PrevisEA Device. All testing met acceptance criteria and demonstrated the PrevisEA Device to be safe and electromagnetically compatible.

5.5 Clinical Testing – PrevisEA Optimization Trial

Clinical data was submitted in support of this 510k Premarket Notification. Clinical testing demonstrated the PrevisEA Device accomplishes its intended use.
Trial Registration: ClinicalTrials.gov NCT03505476

75 subjects undergoing intestinal resection surgery had PrevisEA applied at the completion of surgery.

This study demonstrated the capability of the PrevisEA Device in listening/capturing the acoustic biomarker, MH4 while in clinical use (attached to patient abdomens).

5.6 Conclusion

Since the comparison of bench testing to clinical outcomes is still not well understood for this type of device, clinical testing was required to support substantial equivalence.

The clinical data submitted validates the intended use of the PrevisEA Device. The nonclinical data support the safety and effectiveness of the device, and the bench demonstrates the device meets its own specifications. The hardware and software verification and validation demonstrate that the PrevisEA device performs as intended in the specified use conditions. Though there are minor differences in technological characteristics, the data provided in this submission and the comparisons demonstrate these differences do 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 and reference devices.