January 10, 2022

G-Tech Medical
Steve Axelrod
President and CEO
2495 Hospital Drive, Suite 300
Mountain View, CA 94040

Re: K212954
Trade/Device Name: G-Tech Wireless Patch System (WPS)
Regulation Number: 21 CFR 876.1735
Regulation Name: Electrogastrography System
Regulatory Class: Class II
Product Code: MYE
Dated: September 14, 2021
Received: September 16, 2021

Dear Steve Axelrod:

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)*
K212954

Device Name
The G-Tech Wireless Patch System (WPS)

Indications for Use *(Describe)*
The intended use for the G-Tech Patch System is to serve as a tool that provides gastrointestinal myoelectrical activity measurements to be used at the discretion of the Physician or Clinical User to aid in the diagnosis and evaluation of gastrointestinal disorders.

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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510(K) SUMMARY

This summary of the 510(k) premarket notification for the G-Tech Patch System is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

510(k) Notification K212954

Date:	Jan 7, 2022
Applicant:	G-Tech Medical, Inc. 2495 Hospital Drive, Suite # 300 Mountain View, CA 94040 Phone: 650-269-1479 Fax: N/A
Applicant Contact Person:	Steve Axelrod, PhD President and CEO, G-Tech Medical, Inc. 2495 Hospital Drive, Suite # 300 Mountain View, CA 94040 Phone: 650-269-1479 Fax: N/A Email: steve.axelrod@gtechhealth.com
Device Information	Trade Name: The G-Tech Wireless Patch System (WPS) Generic/Common Name: Gastrointestinal myoelectrical activity measurement system Regulation: 21 CFR 876.1735 Classification: Electrogastrography (EGG) system Product Code: MYE
Predicate Device(s)	**Primary predicate device #1:** DEN990005 / K984637, THE 3CPM EGG MACHINE **Predicate device #2**: K014269, Polygram Net Electrogastrography Application Software, Model 9043S0151; Polygraf Id, Model 9043G0102 **Reference device:** K092342, Smartpill GI Monitoring System, Version 2.0.
Intended Use	The intended use for the G-Tech Patch System is to serve as a tool that provides gastric and intestinal myoelectrical activity measurements to be used at the discretion of the Physician or Clinical User to aid in the diagnosis and evaluation of gastrointestinal disorders.
Device Description	The G-Tech System is a non-invasive wireless gastrointestinal monitoring system for use by the physician or staff in the hospital setting, clinic, or physician's office. The device is intended for use while the patient is under direct supervision

	(e.g., in hospital or clinic) as well as after discharge to home or to intermediate setting. The device is for prescription use only. The device consists of the G-Tech Patch, the G-Tech Patch Monitor, an iOS application, a secure cloud storage server and computer-based data analysis algorithms. The G-Tech Patch is a single use, wearable electrode patch that reads the electrical signals of the gastrointestinal tract from the abdominal skin surface. The Patch transmits the acquired electrical signals via Bluetooth to the G-Tech Patch Monitor. The G-Tech Patch Monitor receives the raw data, encrypts it, and periodically uploads it to a secure cloud server. Additionally, the Patch Monitor has a patient interface to allow the patient to manual enter events such as meals, bowel movements, pain or the taking of medications. Data analysis algorithms process the uploaded data to measure and report myoelectrical activity for the stomach and intestines. These measurements are made available to physicians for aid in clinical evaluation of their patient.
Determination of Substantial Equivalence:	**Indications for Use:** The G-Tech Wireless Patch System and the predicate device have the same indications for use and same intended population. **Technology:** The G-Tech WPS operates on the same fundamental principal as the predicate system by measuring myoelectrical activity with cutaneous electrodes at the abdominal skin surface. Technological improvements in the G-Tech WPS that improve on the predicate system have been evaluated to ensure that the safety and efficacy profile of the predicate device is maintained for the G-Tech Patch System. **Electrical safety and electromagnetic compatibility (EMC)**: Electrical safety and EMC testing were conducted on the G-Tech Wireless Patch System. The G-Tech Wireless Patch System complies with the following standards • IEC 60601-1:2005 • IEC 60601-1-11:2015 • IEC 60601-1-6:2010 • IEC 60601-1- 2:2014 • ANSI C63.27-2017 **Biocompatibility:** The biocompatibility of the G-Tech Patch System was assessed by evaluating the results of the testing recommended by ISO 10993-1:2009, *Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management*. The G-Tech Patch has been assessed to be compliant for contact with intact skin for up to 30 days.

	Software Verification and Validation Testing: The G-Tech Patch System uses software to acquire and process the myoelectrical signals and generate a report for the Physician. Software documentation for the G-Tech Patch System was developed in consideration of FDA's guidance documents, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Content of Premarket Submissions for the Management of Cybersecurity in Medical Devices" and is provided. **Mechanical Strength Testing**: Mechanical Strength testing that includes wear adhesion test and tensile strength test are presented. Additionally, impact test, drop test and shock and vibration tests, conducted for compliance to 60101-1-11 that assesses requirements of medical electrical equipment for Home Healthcare, is presented. The testing demonstrates that the G-Tech Wireless Patch System device should perform as intended in the specified use conditions and maintain the safety profile of the predicate system. **Bench Performance Study**: Functional bench testing performed to demonstrate the performance and efficiency of the patch system and algorithms that calculate myoelectrical activity of the Stomach and Intestines are presented. Known signals that have realistic background, artifact and noise characteristics to the system were applied to the system both directly and through a phantom, to assess how the system will perform when the signals are real and not known *a priori*. The study demonstrated that the G-Tech Patches are reliable and provide consistent electrical measurement devices, and that the data processing algorithms are efficient engines for extracting rhythmic motor activity signals. **Animal Study**: Data from a study undertaken to compare simultaneous measurements between G-Tech Wireless Patches and multi-element electrodes sutured to serosal surfaces of stomach, small intestine, and colon of adolescent Yucatan mini-pigs is presented. The data demonstrate that the slow wave signals associated with the three major GI organs as observed with internal electrodes are detectable at the skin surface with the G-Tech Wireless Patches and have fidelity to the internally measured signals in frequency and spectral shape. **Clinical Studies:** G-Tech Medical has studied its technology under several non-significant risk IRB-approved studies and well-documented case histories. These studies have focused on understanding the measurement capabilities and potential clinical utility of the technology. The primary evidence includes simultaneous measurements between G-Tech Wireless Patches and antroduodenal and colonic manometry that demonstrates that the non-invasive patch system records signals that can be identified as being from the Stomach, Duodenum/Jejunum and Colon by the concordance with frequency and time, of spectral analysis of high-resolution manometry data. Similarly, concordance in frequency and time observed between G-Tech Wireless Patch measurements and Smart Pill measurements is presented that corroborates the findings from the manometry study. The supplemental evidence provided are four peer-reviewed publications listed below. Three of these demonstrate correlation between the G-Tech Wireless Patch Measurements and clinical markers of postoperative recovery in adult and

	pediatric populations. A fourth peer reviewed publication demonstrates reproducibility of the gastric and intestinal myoelectrical profile over multi-year periods and the sensitivity of the measurements to in external stimulus in specific examples. 1. Dua, M.M., Navalgund, A., Axelrod, S., Axelrod, L., Worth, P.J., Norton, J.A., Poultsides, G.A., Triadafilopoulos, G. and Visser, B.C., 2018. Monitoring gastric myoelectric activity after pancreaticoduodenectomy for diet "readiness". *American Journal of Physiology-Gastrointestinal and Liver Physiology*, *315*(5), pp. G743-G751. 2. Navalgund, A., Axelrod, S., Axelrod, L., Singhal, S., Tran, K., Legha, P., & Triadafilopoulos, G. (2019). Colon myoelectric activity measured after open abdominal surgery with a noninvasive wireless patch system predicts time to first flatus. *Journal of Gastrointestinal Surgery*, *23*(5), 982-989. 3. Taylor, J.S., de Ruijter, V., Brewster, R., Navalgund, A., Axelrod, L., Axelrod, S., Dunn, J.C. and Wall, J.K., 2019. Cutaneous Patches to Monitor Myoelectric Activity of the Gastrointestinal Tract in Postoperative Pediatric Patients. *Pediatric gastroenterology, hepatology & nutrition*, *22*(6), pp.518-526. 4. Axelrod, L., Axelrod, S., Navalgund, A. and Triadafilopoulos, G., 2020. Pilot Validation of a New Wireless Patch System as an Ambulatory, Noninvasive Tool That Measures Gut Myoelectrical Signals: Physiologic and Disease Correlations. *Digestive Diseases and Sciences*, pp.1-11.
Conclusion:	The G-Tech Patch System and the predicate device have the same indications for use. Technological improvements in the G-Tech WPS that expand the utility of the predicate device have been evaluated to ensure that the safety and efficacy profile of the predicate device is maintained for the G-Tech Patch System. The biocompatibility, electrical and electromagnetic testing and hardware testing support the safety of the device. The clinical data supports the safety and the ability of the G-Tech Wireless Patch System to measure not just gastric but also intestinal myoelectrical activity. The bench testing, hardware and software verification and validation demonstrate that the G-Tech Wireless Patch System device should perform as intended in the specified use conditions. Therefore, it is the conclusion of G-Tech Medical that the G-Tech Patch System is substantially equivalent to the predicate device.