March 29, 2023

CoapTech Inc.
Jack Kent
Chief Commercialization Officer
101 W. Dickman Street, Suite 700
Baltimore, MD 21230

Re: K223916
Trade/Device Name: PUMA-G System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KGC
Dated: December 28, 2022
Received: December 29, 2022

Dear Jack Kent:

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,

Sivakami Venkatachalam -S

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)*
K223916

Device Name
PUMA-G System

Indications for Use *(Describe)*
The CoapTech PUMA-G System (PUMA-G) is intended to affix the stomach to the anterior abdominal wall facilitating the initial percutaneous placement of a gastrostomy feeding tube in adults and adolescents of sufficient size ("Transitional Adolescent B" patients 18 to 21 years of age with no special considerations compared to adults).

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

(per 21 CFR 807.92)

Submitter Information

Name	CoapTech Inc.
Address	101 W. Dickman Street, Suite 700 Baltimore, MD 21230
Phone Number	(443) 574-6981
Contact Person	Jack Kent, MBA MPH Chief Commercialization Officer
Date Prepared	March 18, 2023

Device Information

Trade Name	PUMA-G System
Common Name	Gastrostomy Aid
Classification	Gastrointestinal tube and accessories 21 CFR 876.5980 (Product Code KGC)

Predicate Device Information

Device Name	PUMA-G System
K Number	K183057

Device Description

The PUMA-G System is a medical device designed to aid in the initial placement of permanent feeding tubes, which are placed via percutaneous gastrostomy. Historically, gastrostomy tubes have been placed using either endoscopy or radiography (e.g., fluoroscopy) for visualization. The PUMA-G System provides visualization by ultrasound, allowing the user to assess the future gastrostomy tract prior to placement. The PUMA-G System contains three main custom components: a balloon catheter, a guidewire, and an external magnet. An internal magnet within the balloon catheter is placed orogastrically into the stomach, where it is pulled up to the anterior abdominal wall by the external magnet. After filling the balloon with fluid, the user's existing ultrasound is used for visualization of the future gastrostomy tract and for ultrasound-guided needle placement. The guidewire is then inserted and snared by the balloon, and the paired unit (balloon catheter and guidewire) is then pulled out the mouth. A gastrostomy tube is then placed using the guidewire and Seldinger technique.

Intended Use

To Aid in Percutaneous Access to the Stomach During Gastrostomy Tube Placement

Indications for Use

The CoapTech PUMA-G System (PUMA-G) is intended to affix the stomach to the anterior abdominal wall facilitating the initial percutaneous placement of a gastrostomy feeding tube in adults and adolescents of sufficient size ("Transitional Adolescent B" patients 18 to 21 years of age with no special considerations compared to adults).

Comparison to Predicate

The PUMA-G System indications for use includes adolescents of sufficient size, meaning patients that are similarly sized to adults.

Technological Characteristics

As shown in Table 1, many technological similarities exist between the subject and predicate devices. The magnetic force was characterized in performance testing to ensure it can adequately create temporary affixture of the tissue (effectiveness) without harming the tissue (safety). Other differences in technological characteristics are minor and/or common to other gastrostomy tube placement devices (e.g., endoscopy).

Table 1: Comparison of Technological Characteristics

Characteristic	**Subject Device** **PUMA-G System**	**Predicate Device (K183057)** **PUMA-G System**	**Comparison**
Mechanism (General)	Mechanical (affix stomach to anterior abdominal wall)	Mechanical (affix stomach to anterior abdominal wall)	Same
Mechanism (Detail)	Magnetic Attraction	Magnetic Attraction	Same
Time	< 10 Minutes	< 10 Minutes	Same
Materials	ISO 10993 Compatible	ISO 10993 Compatible	Same
Sterilization	Ethylene Oxide ISO 11135 Validated	Ethylene Oxide ISO 11135 Validated	Same
Procedural Requirements	Orogastric Over-the-Wire and Pull Tubes Ultrasound Visualization	Orogastric Over-the-Wire Tubes Ultrasound Visualization	Minor Differences No Impact on SE Decision
Performance Testing	Functional Testing Magnetic Characterization Post-Market Analysis	Biocompatibility Sterilization Functional Testing Magnetic Characterization GLP Animal Safety	Equivalent Performance Data Results Show Do Not Raise New or Different Issues of Safety and Effectiveness

Performance Data

Bench performance data were collected to support a substantial equivalence determination. This testing included magnetic force characterization and coupling strength information. Performance test results demonstrate reasonable assurance that the PUMA-G System can effectively bring together the stomach and anterior abdominal wall while maintaining healthy tissue. The PUMA-G System also reliably captures and retains the guidewire for eventual completion of the gastrostomy tube placement. These data suggest the PUMA-G System is as safe and as effective as the identified predicate device.

Conclusions

The PUMA-G System and predicate device have the same intended use and similar indications, both serving as medical devices to aid in the placement of gastrostomy tubes. Based upon analysis and valid scientific evidence, reasonable assurance of safety and effectiveness is apparent, therefore concluding that the PUMA-G System is substantially equivalent to its predicate device.