April 29, 2025

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

Re: K242211
Trade/Device Name: PUMA-G Pediatric System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KGC
Dated: July 26, 2024
Received: July 29, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Anthony Lee -S

Anthony C. Lee, Ph.D., M.B.A.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K242211

Device Name

PUMA-G Pediatric System

Indications for Use *(Describe)*

The CoapTech PUMA-G Pediatric System is intended to affix the stomach to the anterior abdominal wall facilitating the initial percutaneous placement of a gastrostomy feeding tube. The PUMA-G Pediatric System is intended to be utilized in pediatric patients that meet criteria for minimum weight (15 kg) and appropriate abdominal wall thickness (between 0.6 cm and 3.0 cm), as stated in the instructions for 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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510(k) Summary

(per 21 CFR 807.92)

Submitter Information

Name	CoapTech Inc.
Address	101 W. Dickman St, Suite 700 Baltimore, MD 21230
Phone Number	(443) 574-6981
Contact Person	Jack Kent, MBA MPH Chief Commercialization Officer
Date Prepared	April 28, 2025

Device Information

Trade Name	PUMA-G Pediatric System
Common Name	Feeding Tube Placement Aid
Classification	Gastrointestinal tube and accessories
Regulation Number	21 CFR 876.5980
Product Code	KGC
Regulatory Class	II

Predicate Device Information

Device Name	PUMA-G System
K Number	K223916

Device Description

The PUMA-G Pediatric 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 Pediatric System provides visualization by ultrasound, allowing the user to assess the future gastrostomy tract prior to placement. The PUMA-G Pediatric 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 over the guidewire using either the Sachs-Vine PUSH technique or the Ponsky PULL technique.

Intended Use

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

Indications for Use

The CoapTech PUMA-G Pediatric System is intended to affix the stomach to the anterior abdominal wall facilitating the initial percutaneous placement of a gastrostomy feeding tube. The PUMA-G Pediatric System is intended to be utilized in pediatric patients that meet criteria for minimum weight (15 kg) and appropriate abdominal wall thickness (between 0.6 cm and 3.0 cm), as stated in the instructions for use.

Comparison to Predicate

The PUMA-G System indications for use statement is equivalent to the predicate device. Additional conditions for use (weight and abdominal wall thickness) have been added to specify use within the pediatric population.

Technological Characteristics

As shown in Table 1, many technological similarities exist between the subject and predicate device. 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 Pediatric System**	**Predicate Device (K223916)** **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
Coaptation 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 and Pull Tubes Ultrasound Visualization	Same
Performance Testing	Biocompatibility Sterilization Functional Testing Magnetic Characterization Clinical Study	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 and clinical performance data were collected to support a substantial equivalence determination. This testing included balloon performance per ASTM F2528-06, magnetic force characterization (force evaluation and tissue response), coupling strength information, capture reliability, biocompatibility, and sterilization. Performance test results demonstrate scientific evidence that the PUMA-G Pediatric System can effectively bring together the stomach and anterior abdominal wall while maintaining healthy tissue. The PUMA-G Pediatric System also reliably captures and retains the guidewire for eventual completion of the gastrostomy tube placement. These data suggest the PUMA-G Pediatric System is as safe and as effective as the identified predicate device.

Clinical Performance Data

A small safety clinical study was also done, yielding favorable results. This single-center study utilized the PUMA-G Pediatric System on pediatric patients indicated for gastrostomy tube. All patients successfully completed the gastrostomy procedure with no serious adverse events or device-related adverse events. Data was compared to a historical control. The primary endpoint of safely completing the gastrostomy procedure was met. Secondary endpoints also showed a reduction in radiation exposure compared to fluoroscopy-based gastrostomy (historical control). This study did not support use of the PUMA-G Pediatric System in patients under 15 kg or outside the acceptable abdominal wall thickness range (0.6 cm to 3.0 cm), due to low (or lack of) enrollment in these demographics.

Conclusions

The PUMA-G Pediatric 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. Performance testing further confirms that any technological differences do not raise different questions of safety or effectiveness. Bench and clinical performance data were collected and assessed to evaluate the device. This data demonstrates the safety and effectiveness of the PUMA-G Pediatric System. Because the clinical dataset did not include enough enrolled patients at lower weights (under 15 kg), limitations were set within the labeling. Based upon analysis and valid scientific evidence, reasonable assurance of safety and effectiveness is apparent, therefore concluding that the PUMA-G Pediatric System is substantially equivalent to its predicate device.