March 20, 2026

Degania Silicone , Ltd.
Tal Gafni
RA Manager
Degania Silicone Ltd.
Degania Bet, 1513000
Israel

Re: K254170
Trade/Device Name: Percutaneous Endoscopic Gastrostomy (PEG) Kit
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: PIF, KNT
Dated: December 22, 2025
Received: December 23, 2025

Dear Tal Gafni:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 Lee, Ph.D., MBA
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)*
K254170

Device Name
Percutaneous Endoscopic Gastrostomy (PEG) Kit

Indications for Use *(Describe)*
The PEG Catheter Kit is intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition and/or medication to patients requiring nutritional support and gastric decompression. This device is indicated for adult use only.

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) #:

510(k) Summary

Prepared on: 2025-12-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Degania Silicone Ltd.
Applicant Address	Degania Silicone Ltd. Degania Bet Degania Bet 1513000 Israel
Applicant Contact Telephone	+972542033197
Applicant Contact	Dr. Tal Gafni
Applicant Contact Email	tgafni@qmd.net

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Percutaneous Endoscopic Gastrostomy (PEG) Kit
Common Name	Gastrointestinal tube and accessories
Classification Name	Tubes, Gastrointestinal (And Accessories)
Regulation Number	876.5980
Product Code(s)	PIF, KNT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K213356	Entuit PEG	PIF, KNT

Device Description Summary

21 CFR 807.92(a)(4)

The Degania Silicone Percutaneous Endoscopic Gastrostomy (PEG) Kit with ENFit® connection is a single-use, sterile, disposable kit intended for the initial percutaneous endoscopic placement of a feeding tube (PEG catheter) into the stomach of adult patients who require enteral nutrition or medication delivery and cannot be fed orally.

The PEG Kit provides direct access to the stomach through a minimally invasive endoscopic procedure, allowing administration of nutrition, fluids, or medication directly into the gastrointestinal (GI) tract. The system is designed for use in patients with functional GI tracts who are unable to maintain adequate oral intake.

The device is available in two French sizes (20 Fr and 24 Fr) and four configurations, corresponding to the two standard PEG placement techniques:

* Push method – 20 Fr
* Push method – 24 Fr
* Pull method – 20 Fr
* Pull method – 24 Fr

All configurations are supplied sterile (EtO sterilization) and intended for single use.

Each PEG Kit includes:

* A silicone feeding catheter (PEG tube) designed for either the Pull or Push placement method
* A two-way ENFit® connector compliant with ISO 80369-3.
* An external retention device (ERD) to secure the catheter externally

* Tools and accessories for site preparation and tube placement (e.g., guidewire, looped placement wire, scalpel, syringe, hypodermic needles, hemostat, drape, and gauze).

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The PEG Catheter Kit is intended for percutaneous endoscopic gastrostomy placement to provide enteral nutrition and/or medication to patients requiring nutritional support and gastric decompression. This device is indicated for adult use only.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The intended use of the Degania Silicone PEG Kit is identical to the predicate device (Entuit PEG PULL and PUSH Sets, K213356);

Technological Comparison 21 CFR 807.92(a)(6)

The Degania Silicone PEG Kit has the same fundamental technological characteristics as the predicate device, the Entuit PEG PULL and PUSH Sets (K213356). Both devices are silicone-based, sterile, single-use systems designed for percutaneous endoscopic gastrostomy placement using the Pull (Ponsky) or Push (Sachs-Vine) methods. They share the same principle of operation, materials, dimensions, and method of insertion, as well as equivalent components such as the feeding catheter with internal retention dome, external retention system, and guidewire/placement accessories.

The only technological differences are (1) the use of an ENFit®-only connector that complies with ISO 80369-3 to prevent misconnections, replacing the predicate's optional non-ENFit connectors, and (2) a simplified external retention device (ERD) design (silicone bolster with clamp instead of a twist-lock and cable tie). These modifications align the subject device with current international safety standards and do not raise new questions of safety or effectiveness.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Verification and validation activities were conducted to confirm that the PEG Kit meets its design specifications and performs safely and effectively for its intended use. Testing was performed in accordance with FDA-recognized consensus standards and relevant guidance documents, as summarized below:

- Risk Management: Risk management activities were performed per ISO 14971to identify and control hazards, ensuring acceptable residual risk throughout the product lifecycle.
- Biocompatibility: A comprehensive biological evaluation was performed per ISO 10993-1 and FDA's Use of ISO 10993-1 guidance, including chemical characterization, toxicological risk assessment, and testing for cytotoxicity, sensitization, irritation, systemic toxicity, pyrogenicity, implantation, and genotoxicity to confirm the device's biocompatibility for its intended use.
- Sterilization and Residuals: The EO sterilization process was validated following ISO 11135, demonstrating a Sterility Assurance Level (SAL) of 10^{-6}. EO residuals were evaluated and confirmed safe per ISO 10993-7.
- Packaging Validation: Packaging was tested to ensure sterile barrier integrity and shelf life per ISO 11607-1, ISO 11607-2, and accelerated aging guidance (ASTM F1980).
- Transportation and Distribution Testing: Distribution simulation and related packaging tests were performed per: ASTM D4169, ASTM F1886, ASTM F88/F88M, ASTM F1929, ASTM F2098, confirming that packaging and product integrity are maintained during shipping and handling.
- X-Ray Detectability:Radiopacoty was evaluated according to ASTM F640, confirming visibility of device components under clinical imaging conditions.
- ENFit Connector Compliance: Connector dimensions and function were tested to ensure compliance with the ENFit standard using:ISO 20695, ISO 80369-3 and ISO 18250-3, with reference to FDA guidance Safety Considerations to Mitigate the Risks of Misconnections with Small-Bore Connectors.
Testing confirmed correct fit, functionality, and prevention of misconnections.
- MRI Safety: MRI safety and labeling were evaluated according to ASTM F2503-20, ensuring compliance with standardized definitions for MR Safe, MR Conditional, or MR Unsafe device labeling.
- Performance Testing: Bench and simulated-use testing were conducted under internal protocols to confirm the device meets all functional requirements and demonstrates substantial equivalence to predicate devices for its intended use.

No clinical tests were submitted.

Nonclinical testing demonstrated that the Degania Silicone PEG Kit complies with all applicable recognized consensus standards, including ISO 20695 for enteral feeding systems, ISO 80369-3 for ENFit® connectors, and ISO 10993-1 for biocompatibility. The results confirmed that the device meets design and performance specifications for safety, functionality, and packaging integrity. These data support that the Degania Silicone PEG Kit is as safe, performs as intended, and is as effective as the legally marketed predicate device

(Entuit PEG PULL and PUSH Sets, K213356).