May 31, 2024

Degania Silicone Ltd.
Tali Raz
QA&RA Director Endosurgery
Degania Bet 1513000
Israel

Re: K233591
Trade/Device Name: Stylus
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: April 11, 2024
Received: April 30, 2024

Dear Tali Raz:

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.

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

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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K233591

Device Name

Stylus

Indications for Use *(Describe)*

The Stylus is intended to assist in the placement of Low-Profile Gastrostomy Feeding Tube or Gastrostomy Button by providing temporary feeding tube stability during insertion through patient stoma tract.

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.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

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510(k) #: K233591

# 510(k) Summary

Prepared on: 2024-04-15

## Contact Details

21 CFR 807.92(a)(1)

| | |
|---|---|
| Applicant Name | Degania Silicone Ltd. |
| Applicant Address | Degania Bet 1513000 Degania Bet 1513000 Israel |
| Applicant Contact Telephone | +972 -4-6755117 |
| Applicant Contact | Mrs. Tali Raz |
| Applicant Contact Email | traz@qmd.net |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | Stylus |
| Common Name | Stylet, Introducer, Obturator or Stiffener |
| Classification Name | Tubes, Gastrointestinal (And Accessories) |
| Regulation Number | 876.5980 |
| Product Code(s) | KNT |

## Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

| Predicate # | Predicate Trade Name (Primary Predicate is listed first) | Product Code |
|---|---|---|
| K042300 | AMT Introducer | KNT |

## Device Description Summary

21 CFR 807.92(a)(4)

The Stylus (may also be referred as Stylet, Introducer, Obturator or Stiffener) is an Introducer for the Low-Profile Gastrostomy Feeding Tube or Gastrostomy Button (LPGFT/B - K122030) originally cleared in July 2012 which was developed at Degania Silicone Ltd.
The Stylus is made of Polycarbonate (Macrolon®) and has various ranges of lengths, colors and weights.
The Stylus is inserted all the way into the Feeding Port of the LPGFT/B port of the cleared gastrostomy device. The use of the Stylus is optional, it provides stiffness to the LPGFT/B shaft to guide the LPGFT/B through the stoma. The Stylus should not exceed the buttons distal tip. The Stylus is being sterilized by Ethylene Oxide (EtO) along with a compatible Low Profile Gastrostomy Feeding Tube/ Gastrostomy Button kit, rather than a standalone device.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The Stylus is intended to assist in the placement of Low-Profile Gastrostomy Feeding Tube or Gastrostomy Button by providing temporary feeding tube stability during insertion through patient stoma tract.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The intended use of the subject and predicate device is the same, to provide stability to gastrostomy tubes during insertion through stoma.

## Technological Comparison 21 CFR 807.92(a)(6)

The Stylus is made of Polycarbonate (Macrolon®) and has various ranges of lengths. The minor differences in the materials and dimensions of the subject device (compared to the predicate device) do not raise different questions of safety and effectiveness.

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

Bench Performance Testing included tensile strength testing, kink stability testing, stylus stiffness testing, dimensional testing, and gastrostomy compatibility testing. The results show that the device is at least as safe and effective as a legally marketed predicate device.