September 30, 2019

Fidmi Medical Ltd
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, PA 19103

Re: K191844
Trade/Device Name: Fidmi Low Profile Enteral Feeding Device
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: II
Product Code: KNT
Dated: July 9, 2019
Received: July 9, 2019

Dear Janice Hogan:

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
Martha W. Betz, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K191844

Device Name
Fidmi Low Profile Enteral Feeding Device

Indications for Use *(Describe)*

The Fidmi Low Profile Enteral Feeding Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Fidmi Low Profile Enteral Feeding Device Measuring kit is indicated for measuring the length of the stoma prior to placement of a low-profile feeding tube.

The Fidmi Low Profile Enteral Feeding Device Replaceable Tube is intended for use only with the Fidmi Low Profile Enteral Feeding Device, for the replacement of an existing tube. It is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

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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Traditional Premarket Notification Submission – 510(k)
Fidmi Low Profile Enteral Feeding Device
510(k) Number K191844
September 27, 2019

1. SUBMITTER

Fidmi Medical Ltd.
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Caesarea Business Park, Israel 3079500
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2. DEVICE INFORMATION

Device Trade Name:	Fidmi Low Profile Enteral Feeding Device
Classification Name:	Gastrointestinal tube and accessories, 21 CFR 876.5980
Regulatory Class:	Class II
Product Code:	KNT

3. PREDICATE DEVICE

Fidmi Medical Ltd. believes that the Fidmi Low Profile Enteral Feeding Device is substantially equivalent to the following predicate device:

- Boston Scientific Corporation "One Step Button, Low Profile Initial Placement PEG Kit" and the Low Profile Button Replacement Gastrostomy Tube Kit cleared under K161003

4. REFERENCE DEVICE

- Kimberly-Clark MIC-KEY "Low Profile Gastrostomy Tube and Accessories" cleared under K122653

5. DEVICE DESCRIPTION

The Fidmi Low Profile Enteral Feeding Device and its components kits allow for enteral nutrition and / or medication delivery directly into the stomach. The device and components are supplied sterile.

Fidmi Medical's Low-Profile Enteral Feeding Device includes kits for initial placement, replacement of the tube, and complete removal of the gastrostomy tubes.

Fidmi Low-Profile Enteral Feeding Device incorporates three major components:

The Stoma Measuring Device – The Fidmi Medical Stoma Measuring Device is a single use, sterile, disposable device designed for use in the selection of an appropriate length of the Feeding Device to be used exclusively with the Fidmi Low-Profile Enteral Feeding Device.

Low Profile Enteral Feeding Device – The Low Profile Enteral Feeding Device consists of a gastric port that on one side (on the skin surface) includes the flexible external bumper that stabilizes the stoma and keeps the site dry and allows ventilation. On the other side (the stomach side), it includes the bumper that is designed to stay in place and to be dismantled apart for removal when enteral feeding is no longer required.

The Replacement Feeding Tube – The replaceable tubing is designed to be easily replaced when needed. The replacement tube is designed as an internal component that may be retracted, disposed and replaced without any manipulation to the device itself, i.e., the gastrostomy tube implant. It is designed to be replaced by personnel at a medical facility or at a home setting. As depicted in the instructions for use document supplied with the device, it is recommended to replace the tube either upon accidental dislodgement, clogging or once a week.

6. INDICATIONS FOR USE

The Fidmi Low Profile Enteral Feeding Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

Fidmi Low Profile Enteral Feeding Device Measuring kit is indicated for measuring the length of the stoma prior to placement of a low-profile feeding tube.

The Fidmi Low Profile Enteral Feeding Device Replaceable Tube is intended for use only with the Fidmi Low Profile Enteral Feeding Device, for the replacement of an existing tube. It is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.

7. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Fidmi Low Profile Enteral Feeding Device (hereafter the Fidmi device) has the same product code and intended uses as the predicate and reference devices, and the Low-Profile Enteral Feeding Device's principles of operation, functionality and technological characteristics are similar to those of the predicate and reference devices. A comparison table is provided below.

Compared Attribute	Fidmi Low Profile Enteral Feeding Device	EndoVive™ One-Step Button™ and replacement tube (Primary Predicate)	Kimberly-Clark MIC-KEY SF Low Profile Gastrostomy Tube (Reference Device)
510(k) number	K_____	K161003	K122653
Product Code	KNT	KGC and KNT	KNT
CFR	21 CFR§ 876.5980	21 CFR§ 876.5980	21 CFR§ 876.5980
Indications for Use	The Fidmi Low Profile Enteral Feeding Device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means. Fidmi Low Profile Enteral Feeding Device Measuring kit is indicated for measuring the length of the stoma prior to placement of a low-profile feeding tube. The Fidmi Low Profile Enteral Feeding Device Replaceable Tube is intended for use only with the Fidmi Low Profile Enteral Feeding Device, for the replacement of an existing tube. It is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.	The One Step Button device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means. The Percutaneous Stoma Measuring Device is intended to be used to measure the mucosal layers of the stoma prior to placement of the EndoVive One Step Button. The device is indicated for direct feeding The EndoVive Low Profile Replacement Button Gastrostomy device is intended to provide nutrition to a patient directly into the stomach through a stoma. It is indicated for use on patients who are unable to consume nutrition by conventional means.	The Kimberly-Clark MIC-KEY SF Low Profile Gastrostomy Tube and Accessories are indicated for use in patients who require long term feeding, are unable to tolerate oral feeding, who are at low risk for aspiration, require gastric decompression and/or medication delivered directly into the stomach through a secured (initial placement) or formed (replacement) stoma. Kimberly-Clark MIC-KEY SF Over the Wire Stoma Measuring Device is indicated for measuring the length of the stoma prior to placement of a low-profile feeding tube.
Kit contents	Stoma Measuring Device Placement Kit Replacement Kit	One-Step Button Kit Stoma Measuring Device Patient Care Kit (replacement kit)	Stoma Measuring Placement Kit Replacement Kit
Size	Feeding catheter outer diameter 20Fr. Feeding tube length per color	Feeding catheter outer diameter 18Fr. / 24 Fr. (color coded) Low profile Button – 1.2 cm – 4.4	Feeding catheter outer diameter 10Fr. to 24 Fr. Feeding tube length 0.8cm to 6.0 cm to fit different stoma

Compared Attribute	Fidmi Low Profile Enteral Feeding Device		EndoVive™ One-Step Button™ and replacement tube (Primary Predicate)		Kimberly-Clark MIC-KEY SF Low Profile Gastrostomy Tube (Reference Device)
	code:		cm to fit different stoma diameters and lengths.		diameters and lengths (sizes shown below are for the 20Fr. Device)
	Orange	1.8-2.5cm	1.2cm	Supplied with designated Button Spacers available in 1,2,3,4, and 5mm disks that may be used as spacers between the stoma and the external flange of the device.	0.8cm
	Pink	2.5-3.2cm	1.7cm		1.0cm
	Blue	3.2-4.0cm	2.4cm		1.2cm
	Green	4.0-4.7cm	3.4cm		1.5cm
	Yellow	4.7-5.5cm	4.4cm		2.5cm
					3.5cm
					4.0cm
					4.5cm
Sterilization	Sterile device by EtO		Sterile device by EtO / Gamma Irradiation		Sterile device by EtO

8. PERFORMANCE DATA

The Fidmi Low-Profile Enteral feeding Device and components have been tested according to the following standards:

- BS EN 1618:1997 – Catheters other than Intravascular Catheters – Test Methods for Common Properties
- BS EN 1615:2000 – Enteral Feeding Catheters and Enteral Giving Sets for Single Use and Their Connectors – Design and Testing
- ASTM F2528-06(2014) – Standard Test Methods for Enteral Feeding Devices with a Retention Balloon; Procedure A.
- EN ISO 10993-1:2018 Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within A Risk Management Process.
- EN ISO 10993-3:2014 Biological evaluation of medical devices Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity.
- EN ISO 10993-5:2009 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity.
- EN ISO 10993-6:2016 Biological evaluation of medical devices - Biological evaluation of medical devices Part 6: Tests for local effects after implantation.
- EN ISO 10993-10: 2010 Biological Evaluation of Medical Devices – Part 10: Tests for irritation and Skin Sensitization.
- EN ISO 10993-11:2017 Biological evaluation of medical devices – Part 11: Tests for systemic toxicity
- EN ISO 10993-12:2012 Biological evaluation of medical devices – Part 12: Sample preparation and reference materials.
- EN ISO 10993-7:2008:AC 2009 Biological evaluation of medical devices - Part 7: Ethylene Oxide Sterilization Residuals.

The information presented in this submission to support substantial equivalence of the Fidmi Low-Profile Enteral Feeding Device and components to the legally marketed predicate device include device description, indications for use, technological and material comparison, as well as labeling. Bench testing of the Fidmi Low-Profile Enteral Feeding Device and components demonstrates that the device performs as intended and is substantially equivalent. Specifically, the following bench tests were used to establish substantial equivalence:

- Back Flow and Liquid Leakage,
- Dimensional Attributes,
- Functional Evaluation,
- Replaceable Tube & Extension Tube Detachment Force,
- Flow Rate,
- Bond Strength,
- Feeding Device Pullout Force,
- Packaging Integrity and Shelf life Testing, and
- Animal testing.

Fidmi Medical Ltd. has assessed the similarities between the proposed Fidmi Medical Low-Profile Enteral Feeding Device and components, its predicate and reference devices in terms of intended use and technological characteristics while demonstrating the device to be safe and effective as the predicate and reference device(s). The differences in the technological characteristics were found to be minor and do not present any new issues of safety or effectiveness. This evidence supports substantial equivalence between the subject and predicate device, as well as the reference device.

9. CONCLUSION

Fidmi Medical Ltd. has demonstrated that the proposed Fidmi Medical Enteral Feeding Device and components are substantially equivalent to the currently marketed EndoVive™ One-Step Button™ and replacement tube cleared under K161003.