DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2016

Degania Silicone, Ltd.
Zoya Lee
RA CO
Degania Bet
Emek Hayarden
Israel 1513000

Re: K141753
Trade/Device Name: Aquarius™ Nasal Feeding Tube
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tubes and accessories
Regulatory Class: II
Product Code: PIF
Dated: June 30, 2014
Received: June 30, 2014

Dear Zoya Lee:

This letter corrects our substantially equivalent letter of October 16, 2014.

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Benjamin R. Fisher -S

Benjamin Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141753

Device Name
Aquarius™ Nasal Feeding Tubes.

Indications for Use *(Describe)*

The Aquarius™ Nasogastric Tubes are for the administration of nutrition, fluids and/or medications by the natural naso-enteric route for the patients who are physically unable to ingest enough nutrients through normal mastication and deglutition. Nasogastric feeding tube is designated for patients who require intermittent or continues feeding/and or medication into the stomach.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141753

Device Name
Aquarius™ Nasal Feeding Tubes.

Indications for Use *(Describe)*

The Aquarius™ Nasojejunal Feeding Tubes are for the administration of nutrition, fluids and/or medications by the natural naso-enteric route for the patients who are physically unable to ingest enough nutrients through normal mastication and deglutition. Designated for patients who are critically ill and require early enteral feeding/and or medication into the small intestine; may be with a dual tube allowing simultaneous gastric drainage.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) # K141753

510(k) summary

/In accordance to 21CFR Part 807.92/

a) Device name:

- Trade name: Aquarius™ Nasal Feeding Tubes, /Nasogastric & Nasojejunal/
- Common name: Tubes, gastrointestinal
- Regulation description: Gastrointestinal Tube and accessories, 31 CFR 876.5980, code PIF, class II.

b) Submitter name:

Degania Silicone Ltd, Degania Bet, Israel, 1513000,
www.degania-medical.com

Contact person:

Zoya Lee, RA CO, Degania Silicone ltd, Tel: 46726755122,
e-mail: zoya@ds-il.com

c) Identification of Legally Marketed devices:

- DOBBHOFF™ Dual Port Feeding Tube, cleared under 510(k) K112511
- COMPAT Nasojejunal feeding tube, cleared under K961664

d) Device Brief Description

The Aquarius™ Nasal Tube / Nasogastric Tube (NG-Tube) & Nasojejunal Tube (NJ Tube) / are enteral feeding tubes comprised of flexible tubes and ENFit enteral specific connection access. The tubing part of the devices is constructed with radiopaque polyurethane material and with a hydrophilic coating at the distal end to assist the easy insertion of the tube. The Nasogastric Tube may be with metal stylet and/ or with weighted tip to assist the tube insertion and to maintain the tube in the place. The Nasojejunal Tube is with stylet and with radiopaque polyurethane antenna tip at the distal end of the tubing to assist to advance the tube into the jejuna. There is an external marking on both NG & NJ-Tubes for measuring of the tube length inserted into the alimentary tract.

e) Intended Use.

The Aquarius™ Nasal Feeding Tubes, /Nasogastric & Nasojejunal / provide nutritional support for patients who require liquid feedings as a substitution for solid food. Intended for enteral administration of nutrients, fluids and/or medications into alimentary tract via natural naso-enteric route.

f) Indications for Use:

- The Aquarius™ Nasogastric Tubes are for the administration of nutrition, fluids and/or medications by the natural naso-enteric route for the patients who are physically unable to ingest enough nutrients through normal mastication and deglutition. Nasogastric feeding tube is designated for patients who require intermittent or continued feeding/and or medication into the stomach.

- The Aquarius™ Nasojejunal Feeding Tubes are for the administration of nutrition, fluids and/or medications by the natural naso-enteric route for the patients who are physically unable to ingest enough nutrients through normal mastication and deglutition. Designated for patients who are critically ill and require early enteral feeding/and or medication into the small intestine; may be with a dual tube allowing simultaneous gastric drainage.

g) Product Comparison Summary.

The proposed and predicated devices are all intended for providing of nutrients, fluids and/or medications for patients who require liquid feedings as a substitution for solid food. They have the same intended use and similar indication of use, the same general performance characteristic and principle of operations. Used with the connection to the same types of devices.

The placement technique for the proposed Nasogastric Tubes is the same as for the predicate device: insertion of the tube into the patient's stomach through the nasal passage and the esophagus.

The placement techniques for the proposed Nasojejunal Tube are the same: endoscopic, fluoroscopic placement, or preoperative placement as a part of laparotomy.

There are no significant differences that would affect the safety and effectiveness of the Aquarius™ Nasal Feeding Tubes as compared to the predicate devices.

h) Nonclinical testing.

The Aquarius™ Nasal Feeding Tubes have been tested and found to be in compliance with the design and performance requirements according to ISO 80369-1:2010, and EN1615:2000.

The following performance testing was conducted on of the Aquarius™ Nasal Feeding Tubes:

1) Biocompatibility testing (ISO 10993):
   - ✓ ISO 10993-5; Cytotoxicity test
   - ✓ ISO 10993-10: Irritation and sensitization tests
   - ✓ ISO 10993-6: Implantation test
   - ✓ ISO 10993-11: Acute Toxicity test
   - ✓ ISO 10993-3: Mutation Study
2) Leakage testing
3) Stress Cracking
4) Resistance to separation from axial load
5) Resistance to separation from unscrewing
6) Resistance to overriding
7) Disconnection by unscrewing

8) ENFIT dimensional verification
9) Flow rate testing
10) Device dimensional verification
11) Tensile testing
12) Tubing resistance to kinking
13) Misconnection testing
14) Risk Analysis according to ISO 14971:2012

i) Conclusions.

The Aquarius™ Nasal Feeding Tubes (Nasogastric & Nasojejunal) are substantially equivalent to Dobbhoff™ Dual Port Feeding Tubes cleared under 510(k) K112511 and Compat™ Nasojejunal feeding tube cleared under K961664.