Date: July 27, 2014
510(K) # K141631

JUL 2 8 2014

Premarket Notification Summary under 21 CFR § 807.92

a) **Type of 510(k) submission:** Special

b) **Common name:** Feeding Extension Set

c) **Device trade name:** AQUARIUS™ Extension Feeding set

d) **Classification Panel:** 21 CFR 876.5980

e) **Classification Name:** Gastrointestinal tube and accessories

f) **Class:** II

g) **Product code:** KNT

h) **Unmodified/ Predicate device:** 510(k) K132686

i) **510(k) submitter/holder:** Degania Silicone Ltd

j) **FDA Registration Number:** 8030107

k) **Contact person:** Zoya Lee, Regulatory Affairs, e-mail: zoya@ds-il.com, fax: +972 4 675 5155, tel: +972 4 6755122

l) **Device Description:** The Aquarius™ Extension Feeding Set comprise from the hollow Tube with Connector and Funnel at the ends. The *Funnel* connects to delivery source of nutrition and the Connector connects to a gastric feeding device. The Aquarius™ Extension Feeding Set is compatible with Aquarius™ Gastrostomy Button (G-Button) and any gastric feeding device with Mic-Key™ connection ring. A device is for single patient use only.

m) **Indication of Use.** AQUARIUS™ Extension Feeding Set is intended for use as an extension set for AQUARIUS™ G-button/ or other gastric feeding device, incorporating safety connectors which help mitigate the risk of accidental connection of an IV system to the enteral system, or the enteral system to IV system..

n) **Technological Characteristic.** AQUARIUS™ Extension Feeding Set is a substantially equivalent to the unmodified/ predicate device. The only difference between modified and unmodified/ predicate device is in constructive material of the tube and funnel of the device. The hollow tube and funnel of modified device are made of flexible medical grade Polyurethane (PUR) and not from PVC; connector is made from the same acrylonitrile butadiene styrene. No any change in Intention of Use, product design, specification, functional performance, labels and Instruction Of Use.

o) **Non- clinical Summary.** Non- clinical verification of AQUARIUS™ Extension Feeding Set was conducted through biocompatibility and performance functionality testing. The results of Cytotoxicity, Irritation and Sensitization studies according to the standards ISO 10993-5 & ISO 10993-10 have demonstrated the toxicological safety of the proposed devices. The results of the tensile strength, flow rate, and leakage test have demonstrated the compliance with the performance and functionality specification of the device. The results of the mechanical tests according to ISO 80369-1, Annex B and AAMI/ANSI ID54 have demonstrated non-compatibility of the proposed device with female luer connectors and other intravenous sets.

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

July 28, 2014

Degania Silicone, Ltd.
% Zoya Lee
Regulatory Affairs
Kibbutz Degania Bet
Emek Hayarden 1513000
Israel

Re: K141631
Trade/Device Name: AQUARIUS™ Extension Feeding Set
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: II
Product Code: KNT
Dated: June 2 9, 2014
Received: July 1, 2014

Dear Zoya Lee,

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. However, you are responsible to determine that the medical devices you use as components in the kit have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your kit. 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" (21 CFR 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 yours,

Benjamin R. Fisher -S

Benjamin R. 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)*
K141631

Device Name
AQUARIUS™ Extension Feeding Set

Indications for Use *(Describe)*
AQUARIUS™ Extension Feeding Set is intended for use as an extension set for AQUARIUS™ G-button/ or other gastric feeding device, incorporating safety connectors which help mitigate the risk of accidental connection of an IV system to the enteral system, or the enteral system to IV system.

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)*

Benjamin R. Fisher -S
2014.07.28 16:37:16 -04'00'

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