



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

June 21, 2016

Degania Silicone, Ltd.  
Zoya Lee  
RA CO  
Degania Bet  
Emek Hayarden  
Israel 15130

Re: K152246  
Trade/Device Name: Aquarius™ Stoma Measuring Device  
Regulation Number: 21 CFR§ 876.5980  
Regulation Name: Gastrointestinal tube and accessories  
Regulatory Class: II  
Product Code: KNT  
Dated: May 10, 2016  
Received: May 12, 2016

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. 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

## 2. Indications for Use

510(k) Number: K152246

Device Name: Aquarius™ Stoma Measuring Device

**Indication of Use:** The Aquarius™ Stoma Measuring Device is designed to determine the depth (length) of a well-established gastrostomy stoma tract in order to assist in proper length selection of the Aquarius™ Gastrostomy Button (G-Button).  
Intended for transient use (less than 60 minutes).

Prescription Use   X   **ONLY**     
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use     
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) # K152246

Date: June 19, 2016

### 510(k) Summary

- a) **Type of 510(k) submission:** Traditional
- b) **Common name:** Stoma Measuring Device
- c) **Device trade name:** Aquarius™ Stoma Measuring Device
- d) **Classification Panel:** 21 CFR 876.5980
- e) **Classification Name:** Gastrointestinal tube and accessories.
- f) **Class:** II
- g) **Product code:** 78KNT
- h) **Predicate Device:** AMT Balloon Stoma measuring devices, K973893
- i) **Reference Devices:**
  - ✓ All Silicone Foley catheter, 510(k) #K063442
  - ✓ Gastrostomy Replacement Tube, 510(k) #K070124
- j) **510(k) Owner name :** Degania Silicone Ltd, **Degania Bet, Emek Hayarden, Israel, 1513000, tel: +97146755100, fax: +97246709182**
- k) **FDA Registration Number:** 8030107
- l) **Contact person:** Zoya Lee, Regulatory Affairs, e-mail: [zoya@ds-il.com](mailto:zoya@ds-il.com), fax: +972 4 675 5155, tel: +972 4 6755122
- m) **Device Description:** The **Aquarius™ Stoma Measuring Device** comprises a tubular shaft 12 Fr with graduated scale, a funnel with an inflation valve and a retaining balloon. The **Aquarius™ Stoma Measuring Device** is made of 100% silicone, EtO sterilized and for single use. Intended to be use in hospital environment.
- n) **Indication for Use.** The **Aquarius™ Stoma Measuring Device** is designed to determine the depth (length) of a well-established gastrostomy stoma tract in order to assist in proper length selection of the **Aquarius™ Gastrostomy Button (G-Button)**. Intended for transient use (less than 60 minutes).
- o) **Technological and non-clinical summary.** The **Aquarius™ Stoma Measuring Device** is substantially equivalent to the predicate AMT Balloon Stoma measuring device, K973893. There are no significant differences in the design, materials, performance and safe characteristics between subject device and predicate device:
  - ✓ The subject and the predicate devices have the similar design. They both are comprised of a funnel, a tubular shaft and a distal retaining balloon.
  - ✓ The constructive material is the same: silicone rubber
  - ✓ The performance characteristics are the same: inserting of the device via stoma site, anchoring and holding the device by inflated balloon, and reading the measurement of the scale on the shaft.

The indication of use is the same: to determine the depth (length) of a well-established gastrostomy stoma tract in order to assist in proper length selection of the gastrostomy-feeding device.

Non-clinical verification of **Aquarius™ Stoma Measuring Device** was conducted through the risk management process according to ISO 14971:2012 and verification testing. The following verification tests were conducted on the final sterile device.

- ✓ Dimension verification
- ✓ Surface finish and marking inspection
- ✓ Balloon concentricity and balloon bursting volume tests
- ✓ Tensile strength of the tubing part and the connections of the device
- ✓ Packaging tests: visual, tensile strength and dye penetration
- ✓ Shelf life test
- ✓ Biocompatibility evaluation
- ✓ Risk analysis

The test results confirm the compliance of the **Aquarius™ Stoma Measuring Device** with the requirements established by standards.

**o) Conclusion:**

**The Aquarius™ Stoma Measuring Device** is substantially equivalent to AMT Balloon Stoma measuring device cleared under K973893. There are no new questions of safety and effectiveness for **Aquarius™ Stoma Measuring Device** as compared to the predicate devices.