



Food and Drug Administration
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January 20, 2015

Medigus, Ltd.
Sheila S. Stevens, Ph.D.
US Regulatory and Clinical Affairs Consultant
2121 North California Blvd, Suite 290
Walnut Creek, CA 94596

Re: K143634
Trade/Device Name: MUSE System
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODE
Dated: December 19, 2014
Received: December 22, 2014

Dear Sheila S. Stevens,

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

I. Statement of Indications for Use

510(k) Number (if known): K143634

Device Name: MUSE System

Indications for Use: The MUSE System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

II. 510(k) Summary

Medigus Ultrasonic Surgical Endostapler (MUSE™) System

I. SUBMITTER

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Contact Person: Sheila S. Stevens, PhD
US Regulatory and Clinical Affairs

Date Prepared: December 19, 2014

II. DEVICE

Name of Device: Medigus Ultrasonic Surgical Endostapler (MUSE)
Common or Usual Name: Endoscopic Stapling System
Classification Name: Endoscopic Suture/Plication System, Gastroesophageal Reflux Disease (GERD) 21 CFR 876.1500- Endoscope and Accessories
Regulatory Class: II
Product Code: ODE
Special Controls: N/A

III. PREDICATE DEVICE

K132151 Medigus SRS Endoscopic Stapling System (Trade Name MUSE)
This predicate has not been subject to a design-related recall.
No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The MUSE system enables the operator to staple the fundus of the stomach to the esophagus, in 2 or more locations around the esophageal circumference, thereby creating a permanent surgical fundoplication. The procedure is completed entirely through the mouth, without any incisions. The system consists of three main parts: the endoscopic stapler, the control console and several accessories.

The endoscopic stapler is a single use, sterile device (EtO) which resembles an endoscope in appearance and material construction. The distal tip of the device contains a video camera, ultrasonic range finding sight, illumination, irrigation port, insufflation port, and the staple anvil. The distal tip is retroflexed to align with the staple cartridge located in

the shaft of the stapler. An alignment pin in the distal tip is used for initial positioning of the anvil against the cartridge. The cartridge is provided sterile (EtO) and contains standard, 4.8 mm titanium surgical staples. Each application of the device fires five staples in 3 staggered rows. A new cartridge is loaded for each application.

The control console includes the insufflation, light and camera electronics.

The associated accessories include:

- Irrigation bottle with liquids for irrigation of the camera lens
- Silicon tubes for connecting the console and other accessories to the stapler
- Standard overtube for protecting patient's pharynx
- Tweezers to remove and replace staple cartridge
- Staple cartridges

V. INDICATIONS FOR USE

The MUSE System is intended for endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease in patients who require and respond to pharmacological therapy.

The Indications for Use statement for the modified device is identical to that of the predicate.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The modified device shares all technological characteristics with the predicate with the exception of the following differences:

- The subject device provides the option to insufflate with CO₂ or room air whereas the predicate insufflates with room air only.
- The subject device has a smooth alignment pin whereas the predicate device has a screw like alignment pin.
- The subject device has an alternate microprocessor PCB board to accommodate replacements for obsolete electronic components and to enable CO₂ or room air insufflation.
- The subject device has updated software and information screens for the user.
- The subject device has an 18 month expiration date on sterile components whereas the predicate device has a 12 month expiration date.

VII. PERFORMANCE DATA

The following performance data summaries were provided in support of the substantial equivalence determination:

- Electrical safety and electromagnetic compatibility (EMC)
- Software verification and validation testing

- Mechanical Testing
- Animal Model Validation

VIII. CONCLUSIONS

The modified MUSE System has the same intended use, indications, principles of operation and fundamental technology as the cleared, predicate version of the device. The minor differences in the subject device's technological characteristics do not raise any new or different questions of safety or effectiveness. Performance data demonstrates that the subject device performs comparably to the predicate SRS Endoscopic Stapling System that is currently marketed for the same intended use. Thus, the subject device is substantially equivalent to the predicate device.