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

Zutron Medical, LLC
% Mr. Joseph Azary
Senior Regulatory Affairs Consultant
Orchid Design
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Shelton, CT, 06484

JUL 27 2015

Re: K093718
Trade/Device Name: Zutron Medical ZUTR-10003 Endoscope Leak Tester
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: I
Product Code: FCY
Dated (Date on orig SE ltr): November 9, 2009
Received (Date on orig SE ltr): December 9, 2009

Dear Mr. Azary,

This letter corrects our substantially equivalent letter of February 22, 2010.

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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

# Indications for Use

510(k) Number (if known): K093718

Device Name: Zutron Medical ZUTR-10003 Endoscope Leak Tester

Indications For Use: The Zutron Medical ZUTR-1003 Endoscope Leak Tester is designed to detect interior and exterior leaks in endoscopes.

Contraindications: The device is not intended for use in patients.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K093718

**510(k) Summary of Safety and Effectiveness** K093718
**Zutron Medical Endoscope Leak Tester ZUTR-10003**

November 9, 2009

**Submitter:**
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FEB 22 2010

**Manufacturer:**
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**FDA Establishment Registration Number:** 3005299806

***Trade Name, Common Name, Classification:***
Device Trade Name: Endoscope Leak Tester ZUTR-10003

Device Common or Usual Names: Endoscope Leak Tester

Classification: Class I, 21 CFR 876.1500

**Predicate Device:**

- Fujinon Leak Tester – Class 1 Exempt
- SRI Leak Tester – Class 1 Exempt
- Telemed Systems – Class 1 Exempt

**Description of the Device:**
Endoscopes are complex devices that mix mechanical, illumination, optical and video elements, none of which react well to fluid. As a result, endoscope leak testing is a crucial part of proper scope cleaning and disinfection.
The Zutron Medical Endoscope Leak Tester is a leak testing device that detects damage to the interior or exterior of an endoscope.

**Intended Use:**
The Zutron Medical ZUTR-1003 Endoscope Leak Tester is designed to detect interior and exterior leaks in endoscopes.

**Technological Characteristics:**
The Zutron Endoscope Leak Tester is substantially equivalent to the predicate devices. The device has passed internal testing and electrical safety testing requirements.

**Conclusion:**
We believe the subject device is substantially equivalent to the predicate device and conclude that the subject device is as safe and effective as the predicate device.