DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 28, 2015

Advanced Tactile Imaging, Inc.
Vladimir Egorov
CEO
1459 Lower Ferry Road
Trenton, NJ 08618

Re: K142355
Trade/Device Name: Vaginal Tactile Imager
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Dated: April 20, 2015
Received: April 27, 2015

Dear Vladimir Egorov,

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,

Joyce M. Whang -S

for 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

4. Indications for Use Statement

510(k) Number (if known): K142355

Device Name: Vaginal Tactile Imager (VTI)

Indications for Use:

The Vaginal Tactile Imager obtains a high resolution mapping of pressures and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well the analysis information can then be viewed with an intention of assisting in the diagnosis and evaluation. The device is intended for use by physicians, surgeons and medically trained personnel.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary – K142355

5.1. IDENTIFICATION

Submission Date:	August 19, 2014
Applicant's/Owner's Name:	Advanced Tactile Imaging, Inc. 1459 Lower Ferry Rd Trenton, NJ 08618 USA
Contact Person:	Vladimir Egorov
Phone number:	609 333-2127
Fax number:	877 294-6259
Email:	vti@tactile-imaging.com
Device Common Name:	Perineometer
Device Trade/Proprietary Name:	Vaginal Tactile Imager
Device Class:	Class II
Classification Name:	Perineometer
Product Code:	HIR
Regulation Number:	884.1425

5.2. LEGALLY MARKETED DEVICES FOR SUBSTANTIAL EQUIVALENCE

1. K031169, Motility Visualization System (Sierra Scientific Instruments, Inc.)
2. K983052, Peritron Perineometer Model 9300V or 9300A (Cardio Design Pty. Ltd.)

5.3. DESCRIPTION

The Vaginal Tactile Imager (VTI) obtains a high resolution mapping of pressures and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical clinical setting to sense the pressure along the vagina and store the corresponding data. The VTI also provides analysis information. The real time data as well the analysis information can then be viewed by a physician as a tool for diagnosis and analysis.

During the clinical procedure, the probe is inserted in the vagina for measurement of pressures on the vaginal wall at rest and pelvic floor muscle contractile pressures. Real time data is sampled from each sensing element via the VTI interface electronics and made available to the VTI software during each sample period. The software displays the data in real time to support the clinical procedure. The software also supports operational utility functions such as providing the user with an interface for operating the pressure calibration system. It obtains the probe sensor and calibration chamber data during the calibration process and determines the correction factors to be used in subsequent data collection.

The VTI supports physician data analysis by means of a playback function, which replays a stored session using previously recorded data instead of the real time data. The VTI also indicates measured parameters such as high pressure zone location and size, resting pressures, muscle contraction pressures and calculated pressure gradients.

5.4. INTENDED USE

The Vaginal Tactile Imager obtains a high resolution mapping of pressures and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well the analysis information can then be viewed with an intention of assisting in the diagnosis and evaluation. The device is intended for use by physicians, surgeons and medically trained personnel.

The subject device has two intended uses – develop a pressure map of vagina including underlying muscles and measure the strength of the pelvic floor muscles. Each of the primary predicate devices serves as the predicate for one of the intended uses.

The subject device and the Motility Visualization System have the same intended use – develop a pressure map of a tubular structure and its underlying muscles. However, the subject device and the Motility Visualization System are intended for use in different anatomical areas, the vagina and the gastrointestinal tract, respectively.

The subject device and the Peritron Perineometer also have the same intended use – measure the strength of the pelvic floor muscles.

5.5. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The Vaginal Tactile Imager has similar technological characteristics to the Motility Visualization System; however, the two devices differ with respect to the size of the probe, the number of pressure sensors, use of an accelerometer, ability to preheat, and inclusion of accelerometer. However, the differences in technological characteristics do not raise different questions of safety or effectiveness.

5.6. OVERVIEW OF THE PERFORMANCE DATA

The performance testing completed on the Vaginal Tactile Imager included the following:

- Cleaning and high level disinfection validation of vaginal probe
- Biocompatibility testing (cytotoxicity, sensitization, and irritation)
- Electrical safety testing per AAMI/ANSI/IEC 60601-1
- Electromagnetic compatibility testing per IEC 60601-1-2
- Software verification and validation

Four clinical studies were completed with various prototypes of the Vaginal Tactile Imager, including a feasibility study evaluating the final version of the device. The subjects included two groups of women: (1) those with no evidence of pelvic floor disorder and no prior pelvic surgery and (2) those with stage 1 or 2 pelvic organ prolapse. Twenty-two women provided data from 32 procedures with the device. No adverse events were reported. The completed clinical studies demonstrated the following:

- The VTI examination procedure is safe.
- The VTI examination is more comfortable than manual palpation.
- The VTI allows tactile imaging of the vagina, pelvic floor support structures and recoding of pelvic floor muscle contractions.

5.7. CONCLUSION

The Vaginal Tactile Imager is substantially equivalent to the proposed predicate devices.