February 22, 2024

Advanced Tactile Imaging Inc.
Vladimir Egorov
CEO
1457 Lower Ferry Rd
Ewing, New Jersey 08618

Re: K231875
Trade/Device Name: Vaginal Tactile Ultrasound Imager
Regulation Number: 21 CFR 884.1425
Regulation Name: Perineometer
Regulatory Class: II
Product Code: HIR
Received: June 26, 2023

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 (the 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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.

FDA's substantial equivalence determination also included the review and clearance of your Predetermined Change Control Plan (PCCP). Under section 515C(b)(1) of the Act, a new premarket notification is not required for a change to a device cleared under section 510(k) of the Act, if such change is consistent with an established PCCP granted pursuant to section 515C(b)(2) of the Act. Under 21 CFR 807.81(a)(3), a new premarket notification is required if there is a major change or modification in the intended use of a device,

or if there is a change or modification in a device that could significantly affect the safety or effectiveness of the device, e.g., a significant change or modification in design, material, chemical composition, energy source, or manufacturing process. Accordingly, if deviations from the established PCCP result in a major change or modification in the intended use of the device, or result in a change or modification in the device that could significantly affect the safety or effectiveness of the device, then a new premarket notification would be required consistent with section 515C(b)(1) of the Act and 21 CFR 807.81(a)(3). Failure to submit such a premarket submission would constitute adulteration and misbranding under sections 501(f)(1)(B) and 502(o) of the Act, respectively.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jason Roberts -S

Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231875

Device Name
Vaginal Tactile Ultrasound Imager (TIUSv)

Indications for Use *(Describe)*
The Vaginal Tactile Ultrasound Imager obtains high-resolution mapping of pressures, ultrasound images and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures, ultrasound images and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well as 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.

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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1. IDENTIFICATION

Submission Date:	February 22, 2024
Applicant's/Owner's Name:	Advanced Tactile Imaging, Inc. 1457 Lower Ferry Rd Trenton, NJ 08618 USA
Contact Person:	Vladimir Egorov
Phone number:	609 883-0100
Fax number:	n/a
Email:	egorov@tactile-imaging.com
Device Common Name:	Pressure Mapping Perineometer
Device Trade/Proprietary Name:	Vaginal Tactile Ultrasound Imager (TIUSv)
Device Class:	Class II
Classification Name:	Perineometer/Ultrasonic pulsed echo imaging system
Product Code:	HIR/IYO
Regulation Number:	884.1425/892.1560

2. LEGALLY MARKETED DEVICES FOR SUBSTANTIAL EQUIVALENCE

1. K142355, Vaginal Tactile Imager (Advanced Tactile Imaging, Inc.),

3. DESCRIPTION

The Vaginal Tactile Ultrasound Imager (TIUSv) acquires ultrasound images and tactile images (pressure maps) from within the vagina and assesses the strength of pelvic floor muscles within the vagina. The device provides data on the pressures applied to vaginal walls along with the probe location to visualize pelvic floor support structures, and to record pelvic floor muscle contraction. The TIUSv software provides measurement, imaging, and reporting tools. The acquired data and the analysis results provided by TIUSv software can be used by a physician for quantitative biomechanical assessment of the vagina and pelvic floor conditions.

The TIUSv probe is equipped with 96 pressure (tactile) sensors, 192 ultrasound transducers, an orientation sensor (accelerometer), temperature sensors, and micro-heaters. During the clinical procedure, the probe is used to acquire dynamic ultrasound images and pressure responses from the vaginal walls under applied loads. The TIUSv examination procedure includes data collection from all segments of the vagina. Real-time data are sampled from the probe sensors via the interface electronics. The TIUSv software displays the acquired data in real time. The resulting pressure maps (tactile images) of the vagina integrate all the acquired pressure and positioning data for each of the pressure sensing elements. The TIUSv records the dynamic contraction for pelvic floor muscle(s). The probe surfaces that contact the vaginal walls are preheated to human body temperature.

The TIUSv 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 TIUSv also provides data and graphs such as pressure applied to the probe and location, resting pressures, muscle contraction pressures and calculated pressure gradients.

4. INTENDED USE

The Vaginal Tactile Ultrasound Imager obtains high-resolution mapping of pressures, ultrasound images and assesses the strength of pelvic floor muscles within the vagina. It is used in a medical setting to acquire the pressures, ultrasound images and store the corresponding data. It also provides visualization, analysis tools and information. The real time data as well as 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.

5. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

Device & Predicate Device(s):	K231875	K142355	Comment
Device Name	Vaginal Tactile Ultrasound Imager	Vaginal Tactile Imager	-
Primary Product Code	HIR	HIR	Same
Duration of Procedure	Up to 5 minutes	1 - 2 minutes	Similar
Method of Data Collection	Contact tissue surface (vaginal mucosa)	Contact tissue surface (vaginal mucosa)	Same
Handheld Probe	Yes	Yes	Same
Probe Size	17 – 31mm	17 – 31mm	Same
Probe Length	120mm	120mm	Same
Probe Material	Plastic, Silicone	Plastic, Silicone	Same
Pressure Sensor Technology	Capacitive pressure sensor	Capacitive pressure sensor	Same
Number of Pressure Sensors	96	96	Same
Pressure Range	30 kPa	33 kPa	Similar
Pressure Accuracy	0.5 kPa	0.5 kPa	Same
Accelerometer	Yes	Yes	Same
Ultrasound Technology	Yes	No	Different
Number of Ultrasound Transducers	192	N/A	Different
Probe Sterilization	Non-sterile	Non-Sterile	Same
Method of Data Presentation	Pressure color mapped and ultrasound images.	Tactile Images	Similar

Power Source	110 – 240V AC 47 – 63 Hz 1.25 – 0.5A	110 – 240V AC 47 – 63 Hz 1.25 – 0.5A	Same

The Vaginal Tactile Imager has very similar technological characteristics to the subject device, including, the size and material of the probe, the number of pressure sensors, use of an accelerometer, ability to preheat, and the medical diagnostic cart platform.

The Vaginal Tactile Imager (Predicate Device) contains very similar intended use as the subject device except it does not include the use of Ultrasound Imaging capabilities or technology. Both devices develop a pressure map of the vagina to measure the strength of female pelvic floor. Both devices have the same intended user and environment.

The subject device and the Acuson (Reference device) have similar transvaginal ultrasound transducers with B-mode imaging. Additionally, the subject device and the Acuson have very similar Ultrasound arrays with the same number of elements, imaging depth, and frequency bandwidth.

The ArtUs Ultrasound System is used in the subject device to provide B-mode ultrasound imaging. ArtUs ultrasound electronics allows for the reception and conversion of ultrasound signals from the probe's ultrasound array and transmission to the computer on the cart.

The differences between the subject device and the predicate device does not raise any different questions of safety or effectiveness.

6. OVERVIEW OF THE PERFORMANCE DATA

The components of the Vaginal Tactile Ultrasound Imager (TIUSv) were tested individually and together at the system level and the necessary test reports were generated. Other verification reports include the biocompatibility test reports, cleaning and disinfection test reports, applied IEC 60601-1-2 reports and bench verification/validation test reports.

Device Protection against Electrical Shock:	Class IIa
TIUSv probe:	Type B Applied Part
Device IP Code:	IP20
TIUSv probe IP Code:	IP47
Mode of Operation:	Continuous Operation
Sanitary Requirement:	High-level disinfection of TIUSv probe
Power Consumption:	110 W
Input Voltage:	110 - 240 V AC, 47 – 63 Hz, 1.25 – 0.5 A
Weight:	37 kg

Size:	51 cm (width) x 51 cm (depth) x 140 cm (height)
Operational Conditions:	Temperature Range: from 20 ºC to 30 ºC, Relative Humidity Range: 0% - 90%, non-condensing
Methods for device securing against unexpected motion:	Four brakes on cart casters
Measurement Values:	Pressure (kPa) Orientation of the probe (degree), Temperature of the micro-heaters (ºC).
Measurement Ranges:	Pressure: 0 – 30 kPa Orientation: 0 ± 360 degrees for rotation 0 ± 45 degrees for elevation Temperature: from +20 ºC to +40 ºC

Table 1. *Measurement Performance (accuracy) for Pressure*

Pressure range	Accuracy (Calculated by standard deviation for all pressure sensors)	Maximum deviation for individual sensor
0 – 30 kPa	± 0.7 kPa	± 2.5 kPa

Measurement Performance: (accuracy)	Temperature: ± 0.5 ºC Orientation: ± 1.0 degrees
Number Ultrasound Transducers	192 Elements
Ultrasound Frequency	4-7 MHz
Ultrasound lateral resolution	2.0 mm
Ultrasound lateral positioning accuracy	±1.0 mm
Axial resolution	1.0 mm
Ultrasound axial positioning accuracy	±2.0 mm
Calculated Values:	Pressure gradient (kPa/mm) Distance (mm),
Calculated Ranges:	Pressure gradient: 0 – 4 kPa/mm Distance: 0 – 120 mm

Intended Users:	Physicians Surgeons Medically trained personnel

7. PERFORMANCE TESTING

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

Cleaning and High-Level Disinfection

- Cleaning and high-level disinfection validation of vaginal probe

Biocompatibility testing

- The biocompatibility evaluation was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
- Biocompatibility testing (cytotoxicity, sensitization, and irritation) per ISO 10993-1:2009

Electromagnetic Compatibility and Electrical Safety

- The subject device models were assessed for conformity with the relevant requirements of the following standards and found to comply:
- Electromagnetic compatibility testing per IEC 60601-1-2 : 2014/AMD1:2021
- Basic safety and essential performance of medical electrical equipment per IEC 60601-1 2005/AMD1:2012
- Basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment IEC 60601-2-37: 2007/AMD1:2015

Software Verification and Validation Testing

- Software verification and validation testing was conducted and completed, and software documentation was provided as recommended by FDA guidance document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,” dated May 11, 2005 for a moderate software level of concern.
- Software verification and validation IEC/EN 62304:2006+A1:2015

The following quality assurance measures are applied to the development of the system:

- Risk analysis
- Component testing (Verification)
- System performance testing (Verification & Validation)
- Safety testing (Verification)

The nonclinical performance data described above demonstrate the Vaginal Tactile Ultrasound Imager is safe and effective.

8. CONCLUSION

The Vaginal Tactile Ultrasound Imager has the same intended use as the predicate. Performance testing has demonstrated that the subject device is as safe and effective as the legally marketed predicate device.