K103471

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MAR 14 2011

510(k) SUMMARY: UBM Plus

Applicant:	Accutome, Inc.
Address:	3222 Phoenixville Pike Malvern, PA 19355
Contact Person:	Brian T. S. Barrett Manager QA/QC
Telephone:	(610) 889-0200 (610) 889-3233 Fax
Preparation Date:	October 13, 2010
Trade Name:	UBM Plus
Common Name:	Ultrasound B-Scan
Classification Name:	System, Imaging, Pulsed Echo, Ultrasonic (21 CFR 892.1560, Product Code: IYO) Diagnostic Ultrasound Transducer (21 CFR 892.1570, Product Code: ITX)
Legally Marketed Predicate Devices:	Accutome B-Scan Plus (K070943) OTI-Scan 3000 (K092837)
Description of the Device:	The UBM Plus device is designed as a high frequency ultrasound B-Scan, which uses pulsed echo ultrasound to image the anterior segment of the eye. It utilizes a non-contact probe via a contact Scleral shell to generate and receive the ultrasound pulses, and provides a graphic display of returning pulse echoes to indicate the various structures.

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Indications for Use:

The instrument is used for the imaging of the internal structure of the eye including opaque media and anterior segment pathology for the purpose of diagnosing pathological or traumatic conditions of the eye.

Comparison of Technological Characteristics:

The UBM Plus and B-Scan Plus are similar devices in that they are both ultrasonic B-Scans used to image the eye. The UBM Plus has an open tip design with an ultrasonic crystal that resonates at a frequency of 48 MHz, while the B-Scan Plus uses a closed tip design with a single crystal resonating at frequencies of 12 MHZ and 15 MHz. The open tip design of the UBM Plus requires the use of a Scleral Immersion Shell to capture measurements, while the closed tip design of the B-Scan Plus allows for direct contact between the probe and patient without potential injury. The UBM Plus range is fixed at 30mm, while the B-Scan Plus ranges are adjustable with ranges of 30, 50, 60 and 100mm. The UBM Plus runs using an updated software version of the B-Scan Plus. The UBM Plus offers the user the functionality of pan, zoom, annotation, A-Vector, distance/area/angle measurements, 256 grey scale levels, image annotation and gain controls. All of the listed functions are available on the B-Scan Plus, except angle measurements.

The UBM Plus and OTI-Scan 3000 are similar in that they both ultrasonic B-Scans utilizing high frequency probes. The UBM Plus utilizes a frequency of 48 MHz, while the OTI-Scan 3000 utilizes multiple probes with frequencies of 35 MHz and 50 MHz. Both the UBM Plus OTI-Scan 3000 use an open tip design and therefore both require the use of an Immersion Scleral Shell to capture measurements. This is referred to as an immersion cup in the OTI User Manual. The UBM Plus offers the user the functionality of pan, zoom, annotation, A-Vector, distance/area/angle measurements, 256 grey scale levels,

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image annotation and gain controls, all functions available on OTI Scan 3000.

Performance Data:

Non-Clinical Tests:

- IEC 601-1 Medical Electrical Equipment Part 1: General Requirements for Safety
  Result: Compliance with Standard

- IEC 60601-1 Medical electrical equipment Part 1- General Requirements for Basic Safety and Essential Performance
  Result: Compliance with Standard

- IEC 60601-1-1 Medical electrical equipment Part 1-1 - Collateral Standard: Safety Requirements for Medical Electrical Systems
  Result: Compliance with Standard

- IEC EN 60601-1-2:2001 Electromagnetic Compatibility
  Result: Compliance with Standard

- IEC 60601-2-37 Acoustical Measurements
  Result: Compliance with Standard

- NEMA UD2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment
  Result: Compliance with Standard

- NEMA UD3 Standard for Real-Time Display of Thermal and Mechanical Acoustic Output Indices on Diagnostic Ultrasound Equipment
  Result: Compliance with Standard

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- Accuracy Testing (using a Gammex Lesion Phantom and a proprietary measurement phantom)
  Results:

	Accuracy	Accuracy Range
Line	<1%	30mm
Area	<1%	30mm
Angle	<1%	30mm

Clinical Tests:

- Since the UBM Plus uses the same technology as existing devices, clinical tests are not required.

Conclusion:

The UBM Plus is equivalent in safety and efficacy to the legally-marketed predicate devices. Like the predicate devices the UBM Plus successfully passed all the safety, electromagnetic and acoustic output testing. And the accuracy of the UBM Plus is less than 1%, well within acceptable limits.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Accutome, Inc.
% Mr. William Sammons
Responsible Third Party Official
Intertek Testing Services
2307 East Aurora Road; Unit B7
TWINSBURG OH 44087

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Re: K103471
Trade/Device Name: UBM Plus
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYN and ITX
Dated: March 2, 2011
Received: March 3, 2011

Dear Mr. Sammons:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we 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). 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.

This determination of substantial equivalence applies to the following transducers intended for use with the UBM Plus, as described in your premarket notification:

Transducer Model Number

UBM PLUS

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. 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); 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.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Mary S Pastel

Mary Pastel, Ph.D.
Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

1.3 Indications for Use

510(k) Number (if known): K103471

Device Name: UBM Plus

Indications for Use:

The UBM Plus is designed for imaging the internal structure of the eye including opaque media and anterior segment pathology, for the purpose of diagnosing pathological or traumatic conditions in the eye.

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

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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Diagnostic Ultrasound Indications for Use Form

Fill out one form for each ultrasound system and each transducer.

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation									
	A	B	M	PWD	CWD	Color Doppler	Amplitude Doppler	Color Velocity Imaging	Combined (specify)	Other (specify)
Ophthalmic		N								
Fetal										
Abdominal										
Intraoperative (specify)										
Intraoperative Neurological										
Pediatric										
Small Organ (specify)										
Neonatal Cephalic										
Adult Cephalic										
Cardiac										
Transesophageal										
Transrectal										
Transvaginal										
Transurethral										
Intravascular										
Peripheral Vascular										
Laparoscopic										
Musculo-skeletal Conventional										
Musculo-skeletal Superficial										
Other (specify)										

N= new indication; P= previously cleared by FDA; E= added under Appendix E

Additional Comments:_____

(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 Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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