



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center – WO66-G609  
Silver Spring, MD 20993-0002

Accutome, Inc.  
% Mr. Adam Pickholtz  
Quality/Regulatory Manager  
3222 Phoenixville Pike  
MALVERN PA 19355

November 25, 2015

Re: K152573  
Trade/Device Name: 4Sight  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: II  
Product Code: IYO, ITX  
Dated: October 28, 2015  
Received: October 30, 2015

Dear Mr. Pickholtz:

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,

A handwritten signature in black ink that reads "Robert Ochs". The signature is written in a cursive style with a slight shadow effect behind the letters.

Robert Ochs, Ph.D.  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K152573

Device Name

4Sight

Indications for Use (Describe)

The 4Sight is a multi-purpose diagnostic ophthalmic ultrasound system intended to make axial length, anterior chamber depth, lens thickness and corneal thickness measurements of the eye and visualize the internal structure of the eye.

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.

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4Sight  
510(k) Notification

Accutome, Inc.

System: 4Sight

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (A, B)	A
Ophthalmic	Ophthalmic						P	

System: 4Sight  
Transducer: Pachymeter

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	A
Ophthalmic	Ophthalmic							P

System: 4Sight  
Transducer: A-scan

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	A
Ophthalmic	Ophthalmic							P

System: 4Sight  
Transducer: B-scan

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

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	A
Ophthalmic	Ophthalmic	P						



## 510(k) SUMMARY: 4Sight

**Applicant:** Accutome, Inc.

**Address:** 3222 Phoenixville Pike  
Malvern, PA 19355

**Contact Person:** Adam Pickholtz  
Manager QA/QC

**Telephone:** (610) 889-0200  
(610) 889-3233 Fax

**Preparation Date:** 8/10/15

**Trade Name:** 4Sight

**Common Name:** Ophthalmic Diagnostic Ultrasound System

**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:** A-Scan Plus Connect (K123349)  
B-scan Plus (K070943)  
Accupach V Pachymeter (K042752)

- No prior FDA submissions have been submitted for a combination unit by Accutome, Inc.

**Description of the Device:** The 4sight device is designed to combine the functionalities of Accutome's A-scan Plus (K123349), B-scan Plus (K070943) and Accupach Pachymeter (K042752) devices into a combined, stand-alone platform.

The device performs axial length measurements, corneal thickness measurements and images the internal structure of the eye using these 3 modalities.

The 4Sight is a stand-alone system which runs on a Windows 8 platform consisting of a 4Sight control unit, transducers, footswitch, and keyboard.

**Indications for Use:**

The 4Sight is a multi-purpose diagnostic ophthalmic ultrasound system intended to make axial length, anterior chamber depth, lens thickness and corneal thickness measurements of the eye and visualize the internal structure of the eye.

**Comparison of Technological Characteristics to the predicate device:**

All of the critical functions of the 4Sight device are calculated in exactly the same manner as in the predicate devices. The A-scan, B-scan, and pachymetry probes used with the 4Sight are exactly the same as the probe used on the predicate devices. The software algorithms for clinically critical functions, i.e. to process ultrasound measurements and calculate intraocular lens parameters remain exactly the same as in the predicate devices.

The new standalone 4Sight model uses a standalone control unit as the main computing vehicle and display instead of the personal computer. The software modifications in the 4Sight model are those necessary to interface the processing, data storage, display, and printing capabilities of a combined, standalone control unit.

The 4Sight control unit consists of (4) printed circuit boards enclosed in a plastic case. This includes a 1 PCB for power management, 1 PCB to control the pachymeter function, 1 PCB to control the A-scan function and 1 PCB to act as a connector board. The PCB for A-scan functionality is unchanged from the A-scan Plus Connect predicate device.

The energy source for the 4Sight is AC to DC adapter used to power the Accupach Pachymeter predicate device.

The chemical composition of patient contact materials is identical to that of the predicate device as the probes have not changed.

**Standards Testing:**

EN 60601-1 Medical Electronic Equipment Part 1: General Requirements for Safety

Both this device and the predicates were tested to, and found to be compliant with EN 60601-1.

EN 60601-1-2 Collateral Standard: Electromagnetic Compatibility – Requirements and Tests

Both this device and the predicate were tested to, and found to be compliant with EN 60601-1-2.

IEC 60601-2-37 - Safety of Ultrasonic Medical Diagnostic and Monitoring Equipment

Acoustic Measurements for the predicate devices have been evaluated by Acertara Laboratories and Sonora Laboratories.

EN/ISO 10993 - Biological Evaluation of Medical Devices

The same probes are used with this device as with the predicate device which were tested to ISO10993; the materials have not changed.

**Verification Testing:**

A-scan Physical Accuracy Test

This test compares the distance measured ultrasonically by the A-Scan function on the 4sight and the physical distance measured by a mechanical dial indicator. The test results for both the A-Scan function and the predicate device were well within the 0.1mm acceptance criteria.

Results:

Both the A-scan Plus Connect model and the predicate device were well within the 0.1mm acceptance criteria.

Pachymetry Comparison Test: Accupach VI (predicate) vs. 4Sight

The objective of this test is to compare critical parameter results between the two devices under conditions of the same input test fixture and values.

Results:

All of the data met the established acceptance criteria

**Validation Testing:**

Internal Validation Tests

A test plan was developed to evaluate proper operation and usability for all device modes/options.

Results:

All operations and features were fully functional. There were no errors or deficiencies in the patient information. The usability was judged to be equivalent to the predicate device.

Software Validation Testing

317 software requirements specified in the software requirement specification were tested and validated during the software validation process.

All software bugs discovered during the validation process, with the exception of one minor anomaly, were corrected during the process.

External Validation Tests

A checklist was developed which requests quantified critique regarding the safety, functionality and usability of the device. A Rating Scale from 1 to 5 was used with: 5 = best, very user friendly, no problems; and 1 = not acceptable, very unfriendly, significant problem that must be corrected.

Results:

The device was evaluated at 4 different locations by experienced technicians/ophthalmologists.

Safety was ranked 5 by every user. The “Overall Rating” of the device was 4 or 5 by all users. There were no ratings of 1 or 2 in any of the tests.

Validation Tests Summary

The internal and external validation tests demonstrate along with risk analysis and testing to applicable standards that there are no known safety issues with the 4Sight device.

The tests further demonstrate that there are no significant functionality issues and that the usability of the device is equivalent to that of the predicate device.

**Conclusion:**

The positive results of the testing above, along with the risk analysis performed, demonstrate that the 4Sight is at least as safe and as effective as the predicate devices.