



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

ArcScan, Inc.  
% Mr. John Mann  
Director RAQA  
Evergreen Research  
433 Park Point Drive, Suite 140  
GOLDEN CO 80401

February 2, 2016

Re: K153416  
Trade/Device Name: ArcScan Insight 100  
Regulation Number: 21 CFR 892.1560  
Regulation Name: Ultrasonic pulsed echo imaging system  
Regulatory Class: II  
Product Code: IYO, ITX  
Dated: January 12, 2016  
Received: January 13, 2016

Dear Mr. Mann:

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 and is positioned above the typed name.

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)

**K153416**

Device Name

ArcScan Insight 100

Indications for Use (Describe)

The ArcScan Insight 100 is indicated for use in adults to measure dimensions of components of the human eye. To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and structures, such as anterior chamber depth, angle-to-angle width and sulcus-to-sulcus width. Measurements can be made of the cornea and its individual layers including the epithelium, stroma, and surgically induced surfaces. Measurement also may be made of pathological structures such as solid masses or cysts and it is therefore useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

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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# Diagnostic Ultrasound Indications for Use

System: ArcScan Insight 100

Transducer: Blatek AT20573

Intended Use: The ArcScan Insight 100 is indicated for use in adults to measure dimensions of components of the human eye. To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and structures, such as anterior chamber depth, angle-to-angle width and sulcus-to-sulcus width. Measurements can be made of the cornea and its individual layers including the epithelium, stroma, and surgically induced surfaces. Measurement also may be made of pathological structures such as solid masses or cysts and it is therefore useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

| Clinical Application   |                                 | Mode of Operation |   |     |     |               |                    |                  |
|------------------------|---------------------------------|-------------------|---|-----|-----|---------------|--------------------|------------------|
| General (Track 1 Only) | Specific (Tracks 1 & 3)         | B                 | M | PWD | CWD | Color Doppler | Combined (Specify) | Other* (Specify) |
| Ophthalmic             | Ophthalmic                      | P                 |   |     |     |               |                    | A-mode (P)       |
| Fetal Imaging & Other  | Fetal                           |                   |   |     |     |               |                    |                  |
|                        | Abdominal                       |                   |   |     |     |               |                    |                  |
|                        | Intra-operative (Specify)       |                   |   |     |     |               |                    |                  |
|                        | Intra-operative (Neuro)         |                   |   |     |     |               |                    |                  |
|                        | Laparoscopic                    |                   |   |     |     |               |                    |                  |
|                        | Pediatric                       |                   |   |     |     |               |                    |                  |
|                        | Small Organ (Specify)           |                   |   |     |     |               |                    |                  |
|                        | Neonatal Cephalic               |                   |   |     |     |               |                    |                  |
|                        | Adult Cephalic                  |                   |   |     |     |               |                    |                  |
|                        | Trans-rectal                    |                   |   |     |     |               |                    |                  |
|                        | Trans-vaginal                   |                   |   |     |     |               |                    |                  |
|                        | Trans-urethral                  |                   |   |     |     |               |                    |                  |
|                        | Trans-esoph. (non-Card.)        |                   |   |     |     |               |                    |                  |
|                        | Musculo-skeletal (Conventional) |                   |   |     |     |               |                    |                  |
|                        | Musculo-skeletal (Superficial)  |                   |   |     |     |               |                    |                  |
|                        | Intravascular                   |                   |   |     |     |               |                    |                  |
| Other (Specify)        |                                 |                   |   |     |     |               |                    |                  |
| Cardiac                | Cardiac Adult                   |                   |   |     |     |               |                    |                  |
|                        | Cardiac Pediatric               |                   |   |     |     |               |                    |                  |
|                        | Intravascular (Cardiac)         |                   |   |     |     |               |                    |                  |
|                        | Trans-esoph. (Cardiac)          |                   |   |     |     |               |                    |                  |
|                        | Intra-cardiac                   |                   |   |     |     |               |                    |                  |
|                        | Other (Specify)                 |                   |   |     |     |               |                    |                  |
| Peripheral Vessel      | Peripheral vessel               |                   |   |     |     |               |                    |                  |
|                        | Other (Specify)                 |                   |   |     |     |               |                    |                  |

N = new indication; P = previously cleared by FDA; E = added under this appendix \* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

# 510(k) Summary ArcScan Insight 100™

## **SUBMITTER INFORMATION**

Company name / address                      ArcScan, Inc.  
433 Park Point Drive  
Golden CO 80401

510(k) contact name / numbers              Andy Levien  
Phone +1 877.363.7226  
[alevien@arcscan.com](mailto:alevien@arcscan.com)

Date summary prepared                        11/23/2015

## **DEVICE IDENTIFICATION**

Trade names                                      ArcScan Insight 100™

Common name                                    Ultrasound Bio Microscope

Classification name                            Ultrasonic pulsed echo imaging system, 90-IYO,  
892.1560  
Diagnostic ultrasonic transducer, 90-ITX, 892.1570

## **PREDICATE DEVICE**

Trade names                                      Artemis VHF Ultrasonic Arcscan System (Artemis  
2)

510(k) number                                    K021333

## **DEVICE DESCRIPTION**

ArcScan Insight 100 is a precision ultrasound device for imaging and biometry of the eye. It uses a 20-60 MHz transducer that scans the eye in an arc whose curvature approximates the anterior ocular surfaces. Specifically, the ArcScan Insight 100 can measure the thickness of the cornea and its individual layers, the epithelium, stroma, and surgically induced surfaces. Measurements can also be made of the anatomic structures comprising the anterior of the eye such as anterior chamber depth, angle-to-angle width, and sulcus-to-sulcus width. Measurements can be made of pathologic structures such as solid masses and cysts.

## **INDICATION FOR USE**

The ArcScan Insight 100 is indicated for use in adults to measure dimensions of components of the human eye. To provide tomographic, high-resolution ultrasound images of the anterior portion of the eye. It is also designed to measure these tissues and structures, such as anterior chamber depth, angle-to-angle width and sulcus-to-sulcus width. Measurements can be made of the cornea and its individual layers including the epithelium, stroma, and surgically induced surfaces. Measurement also may be made of pathological structures such as solid masses or cysts and it is therefore useful in evaluation and/or planning of refractive surgery and evaluation of pathologies of the anterior segment such as trauma, tumors, cysts, glaucoma and hypotony.

## **TECHNOLOGICAL CHARACTERISTICS COMPARISON**

Substantial Equivalence: The ArcScan Insight 100 is substantially equivalent to the classified device described in CFR 21.891.1560, "Ultrasonic Pulsed Echo Imaging System" and to other ultrasound systems that have been cleared by the 510(k) process, particularly the Artemis™ VHF Ultrasonic Arc-scan System cleared by ArcScan, Inc. (formerly Ultralink LLC) in K021333.

The 510(k) Substantial Equivalence Decision-making Process (detailed) from The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] was followed as described below:

1. These products have the same intended use, to produce high-resolution ultrasound images of the anterior portion of the eye, and to measure these tissues such as the thickness of the cornea and its individual layers, the epithelium stroma and surgically induced surfaces. They can also be used to measure pathologic structures such as solid masses or cysts.
2. The products have the same fundamental scientific technology.
3. The technological characteristics of this device are the same as those for the predicate device except for the method by which the larger radius of motion is achieved.
4. The acoustic output of this device is similar to that of predicate devices and is well below the preamendment levels described in the guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."
5. The products have the same sterility assurance level of SAL10<sup>-6</sup>.
6. The products have the same biocompatibility for the patient contact surfaces.

## **PERFORMANCE DATA**

The ArcScan Insight 100 complies with IEC 60601-1, Ed. 3: Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance; Corrigendum 1(2006): Corrigendum 2 (2007). The ArcScan Insight 100 complies with IEC 60601-1-2 Ed 3.0: Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests. IEC 60601-1, General Electrical Safety.

The ArcScan Insight 100 Acoustic Power was demonstrated to be less than the preamendment levels for Track 1.

The ArcScan Insight 100 measurement performance capability was demonstrated to meet specifications for the following characteristics:

- Axial resolution
- Lateral resolution
- Thickness measurement
- Lateral measurement

## **CONCLUSION**

The ArcScan Insight 100 is substantially equivalent to the ArcScan Artemis 2.