ASCEND HIT
% Robert A. Miller
Director of Quality Assurance and Regulatory Affairs
801 Warrenville Road, Suite 200
LISLE IL 60532

February 14, 2020

Re: K192372
Trade/Device Name: ASCEND Image Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 13, 2020
Received: January 16, 2020

Dear Mr. Miller:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192372

Device Name
ASCEND Image Viewer

Indications for Use *(Describe)*
ASCEND Image Viewer is a software-only medical device intended for use by trained clinicians to display medical images. ASCEND Image Viewer provides viewing of and measurements on echocardiograms from compatible ultrasound systems that support transthoracic echocardiogram, transesophageal echocardiogram, stress echocardiogram, cath, and vascular study types.

ASCEND Image Viewer is for prescription use only.

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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Section 1

K192372

510(k) Summary

(as required by 21 CFR 807.92)

Date: 20-Jan-2020

A. Submitter's Information:

Name:	ASCEND HIT
Address:	801 Warrenville Road Suite 200 Lisle, Illinois 60532 USA
Telephone Number:	(844) 413-2610
Contact Name:	Andy Miller
Contact Email address:	amiller@ascendhit.com

B. Device Information

Proprietary Name:	ASCEND Image Viewer
Common or Usual Name:	Image Processing System
Classification:	Class II 21 CFR 892.2050 LLZ
Classification Panel:	Radiology
Substantial Equivalence:	ASCEND Image Viewer is substantially equivalent to TomTec Arena (K132544)

Indications for Use:

ASCEND Image Viewer is a software-only medical device intended for use by trained clinicians to display medical images. ASCEND Image Viewer provides viewing of and measurements on echocardiograms from compatible ultrasound systems that support transthoracic echocardiogram, transesophageal echocardiogram, stress echocardiogram, cath, and vascular study types.

ASCEND Image Viewer is for use by prescription only.

Intended Use:

The Ascend device is intended for diagnostic review, quantification and reporting of cardiovascular structures and function of patients with suspected disease to support physicians in diagnosis.

Device Description:
The ASCEND Image Viewer is a Medical Device for viewing and measuring cardiovascular echocardiograms in DICOM format.

The software has features for displaying and measuring cardiovascular images acquired from echocardiograms. Images supported include:

- 2D
- Color Doppler
- M-mode
- Spectral Doppler (Pulsed Wave and Continuous Wave)

The ASCEND Image Viewer provides Cine play review and control.

Standard Review supported study types include:
- TTE
- TEE
- Cath
- Stress Echo
- Vascular

Supported Measurements include:
- Linear
- Volume (method of discs)
- Velocity time integral
- Pressure half-time
- Area
- Time
- Velocity
- Angle (measurement of two lines with a common vertex drawn on the image)

The user can make measurements which persist for later use within the ASCEND Image Viewer.

Operator profile
The device is generally used by medical professionals such as doctors and sonographers in need of displaying echocardiograms for diagnostic purposes.

Intended use environment

The software is intended to be used in Health Care facilities including Office environments within hospitals and clinics.

Operating principle

- On desktop PCs the interaction with the software is mainly performed with mouse and/or keyboard

Primary operating functions

Diagnostic viewing of echocardiograms in ultrasound DICOM format.

C. Technological Characteristics of the Device as compared to Predicate Device:

	Predicate Device **TomTec-Image Arena TomTec Imaging Systems GmbH (K132544)**	**Subject Device** **ASCEND Image Viewer Ascend HIT**	**Substantially Equivalent**
Software only device	Yes	Yes	Yes
Web accessible	Yes	Yes	Yes
Display Images	still images and image sequences	Yes	Yes
Select Images for closer examination	Yes	Yes	Yes
Echocardiogram analysis and review capability	**Manual only**	**Manual**	**Yes**
Data Source	Multiple modalities	Ultrasound	Yes
DICOM compliant	Yes	Yes	Yes
Ultrasound mode utilized for echo analysis	B mode	2D, Color Doppler, M-mode, Spectral Doppler images.	Yes
Viewing mode – 2D	Yes	Yes	Yes
Viewing mode – 3D	Yes	No	No

General Cardiac Measurements	• Distance • **LV distance** • Angle • Area • **Elipse** • Disks • Time • Velocity • **Heart rate** • **Acceleration** • PHT • VTI • **PIRI** • **Slope**	Linear (distance) Angle Area Volume (method of disks) Time Velocity VTI PHT	Yes – Different features from predicate have been verified and validation to assure that there is no impact on safety and effectiveness.
Display format	• AVI, BMP, JPEG or DCM export	Yes	Yes
Minimum Hardware Requirements			
Operates on off the shelf hardware	Yes	Yes	Yes
OS	Microsoft Windows	Microsoft Windows 7 and above.	Yes

D. Brief Discussion of Test Results Submitted:

Bench Testing

The test plan covers all aspects of the functionality, exercising every user interface, all menus and submenus, as well as the measurement tools.

The software was tested according to the company's Design Control process. Risks were analyzed according to ISO 14971 to find risks in the non-acceptable area. No risks have been identified in the non-acceptable area. Hence, no measures are considered essential performance characteristics. The software is also verified for compliance with the DICOM standard.

Clinical Testing

ASCEND Image Viewer was tested in US city-hospital environments throughout the development cycle. Clinical testers consisted of resident cardiologists, cardiology fellows, and sonographers. The clinical test results showed ASCEND Image Viewer performed effectively its intended use. Where the functionality of ASCEND Image Viewer intersected with the predicate device, it was found to be substantially equivalent. No late-arising risks or other safety concerns were recorded during clinical testing.

E. Conclusions from Test Results:

The Graphic User Interface conforms to the ASCEND Image Viewer functional specification.

The comparison ASCEND Image Viewer with the predicate devices shows that the ASCEND Image Viewer has similar functionality, intended use, technological characteristics, and typical users as the predicate devices. Verification and validation activities ensure that the design specifications are met, and that ASCEND Image Viewer does not introduce new issues concerning safety and effectiveness. Hence ASCEND Image Viewer is substantial equivalent to the predicate device.