Argus Cognitive, Inc.
℅ Andrea Marosan
Official Correspondent
Dartmouth Regional Technical Center
16 Cavendish Court
LEBANON NH 03766

June 24, 2023

Re: K223322
Trade/Device Name: Argus Cognitive ReVISION Software Application
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 16, 2023
Received: June 16, 2023

Dear Andrea Marosan:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223322

Device Name
Argus Cognitive ReVISION Software Application

Indications for Use *(Describe)*
Indications for use of the Argus Cognitive ReVISION Software are quantification and reporting of right ventricle (RV) structures and function of patients (adults only) with suspected disease to support physicians' diagnosis.

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.

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510(k) Notification K223322

GENERAL INFORMATION [807.92(a)(1)]

Applicant:

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Date Prepared: June 16, 2023

DEVICE INFORMATION [807.92(a)(2)]

Trade Name:

Argus Cognitive ReVISION Software Application

Generic/Common Name:

Image review and quantification software

Classification:

21 CFR 892.2050, Medical image management and processing system

Product Code:

LLZ, System, Image Processing, Radiological

PREDICATE DEVICE(S) [807.92(a)(3)]

K150122 – TomTec-Arena TTA2

DEVICE DESCRIPTION [807.92(a)(4)]

The Argus Cognitive ReVISION Software ("ReVISION Software") assesses global and segmental function of the right ventricle (RV) of the heart via the decomposition of longitudinal, radial, and anteroposterior motions of the RV walls and quantifies their relative contribution to global RV ejection fraction along with longitudinal, circumferential and area strains using 3D datasets obtained by echocardiography. Segmentation is performed on the end-diastolic 3D RV model using a rule-based, non-AI/ML algorithm to have 15 RV segments. This segmentation is then projected to all models in the corresponding cardiac cycle.

INDICATIONS FOR USE [807.92(a)(5)]

Indications for use of the Argus Cognitive ReVISION Software are quantification and reporting of right ventricle (RV) structures and function of patients (adults only) with suspected disease to support physicians' diagnosis.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES [807.92(a)(6)]

Please refer to **Table 2: Substantial Equivalence Table**.

SUBSTANTIAL EQUIVALENCE

The proposed indications for use for the Argus Cognitive ReVISION Software is substantially equivalent to the indications for use for the predicate device. Any differences in the technological characteristics between the devices do not raise any new or different questions of safety or effectiveness. Thus, the Argus Cognitive ReVISION Software is substantially equivalent to the predicate device.

PERFORMANCE DATA [807.92(b)]

All necessary software testing was conducted on the Argus Cognitive ReVISION Software to support a determination of substantial equivalence to the predicate device. The testing followed internal company procedures. Software testing was carried out at the module and system levels, following predefined test protocols.

Nonclinical Testing Summary [807.92(b)(1)]:

All necessary performance testing was conducted on the Argus Cognitive ReVISION Software to support a determination of substantial equivalence to the predicate device. Testing acceptance criteria have been predefined in all test protocols to ensure that the subject device is safe and effective. Software verification was performed according to the standard IEC 62304:2005, *Medical device software – Software lifecycle processes*. Usability testing was performed according to IEC 62366-1:2015, *Medical devices – Part 1: Application of usability engineering to medical devices*. The collective results of the non-clinical testing demonstrate that the Argus Cognitive ReVISION Software meets the established specifications and complies with the aforementioned standards.

The nonclinical testing is summarized in **Table 1: Summary of Testing Performed**.

Table 1: Summary of Testing Performed

Test	Acceptance Criteria	Result
Unit/Integration Testing		
Mesh Processing	Mesh orientation parameters for apex, inflow, and outflow centers are within specifications.	Pass
Volume Calculation	Volume calculations are consistent with predicate device and are reproducible.	Pass
Motion Decomposition	Interobserver and intraobserver variability of decomposed end-systolic volumes are within specifications. Pre- and postoperative values for ejection fraction are reproducible.	Pass
Volumetric Segmentation	The relative volumes of each segment to the total volume fall within specifications. The sum of segmental volumes is equal to the global volume. Interobserver and intraobserver variability of segmental end-diastolic and end-systolic volumes are within specifications.	Pass
3D Strain Calculation	Septal and free wall longitudinal strain, and global circumferential strain values are consistent with predicate device. Interobserver and intraobserver reliability of global longitudinal strain are within specifications.	Pass
Verification Tests	Global and segmental metrics are calculated in more than 99% of cases. When inadequate input is presented, the data is not analyzed and an error message is presented. Movement decomposition and volume calculations of known geometric data are accurate.	Pass
Mathematical Unit Tests	The area of a two-dimensional polygon is calculated accurately. The relations between a two-dimensional line or a three-dimensional plane and a point are calculated accurately. The closest point on a line, segment, ray, or plane to a given point is calculated accurately. The distance between two points, a segment and a point, a line and a point, a ray and a point, a plane and a point is calculated accurately. The collinearity of three points or of two lines is calculated accurately. The relation of a point to another point, line, segment, ray, plane, or polygon is calculated accurately. The intersection point of two lines, a line and a triangle, a line and a plane, a ray and a triangle, a ray and a plane is calculated accurately. The intersection of two segments, a segment and a line, a segment and a plane, a segment and a ray, a segment and a triangle is calculated accurately. The points of a polygon are not duplicated and are labeled accurately.	Pass
Evaluation Time	Average evaluation time must be under 15 minutes.	Pass
System Leveling Testing		
Response Time	Response time must be under 10 seconds.	Pass
Response to Stress Conditions	No delay in the ReVISION Software functionality.	Pass

Validation Testing		
Accuracy Validation	30 subjects (10 healthy adults, 10 adult subjects with established cardiac diseases but maintained right ventricular ejection fraction, and 10 adult subjects with established cardiac diseases and reduced right ventricular ejection fraction) were randomly selected from a comprehensive clinical database of 811 retrospective subjects with available echocardiographic data. The accuracy of segmental volumes, EFs, and strains was evaluated by 3 expert cardiologists with expertise in 3D echocardiography who was blinded to ReVISION Software results. The cardiologists manually performed segmentation and contouring on the same 3D models that were analyzed by ReVISION Software. Acceptance criteria for this validation was <30% relative difference for each of the segmental metrics between the ReVISION Software and the manual measurements performed by the cardiologists. The accuracy of global longitudinal and circumferential strains were also evaluated by the expert cardiologists who created longitudinally and circumferentially oriented contours using manual labeling. Acceptance criteria for this validation was <10% relative difference in global strain values between the ReVISION Software and the manual measurements performed by the cardiologists. In order to validate that decomposed ejection fractions (LEF, REF, AEF) are calculated based on such 3D models that are indeed shortened in the given direction only (i.e., longitudinal, radial, and anteroposterior), we created a test pipeline for expert human readers. By overlaying the decomposed end-systolic 3D surface to the end-diastolic 3D surface using the test population's 30 cases, the expert cardiologists' task was to verify visually that the decomposition direction indeed corresponds to the desired one. Acceptance criterion was that the 3D model shortens only in the corresponding direction in 100% of the cases.	Pass
Database Validation	Using the retrospective 3D echocardiographic clinical database of 811 subjects, the following parameters were evaluated by the ReVISION Software and by the predicate device. Acceptance criteria for this comparison were: 1. ReVISION-derived end-diastolic volume (EDV) has a clinically negligible bias compared with the TomTec-derived EDV 2. ReVISION-derived end-systolic volume (ESV) has a clinically negligible bias compared with the TomTec-derived ESV 3. ReVISION-derived stroke volume (SV) has a clinically negligible bias compared with the TomTec-derived SV 4. ReVISION-derived ejection fraction (EF) has a clinically negligible bias compared with the TomTec-derived EF 5. ReVISION-derived global longitudinal strain correlates with TomTec-derived EF 6. ReVISION-derived global circumferential strain correlates with TomTec-derived EF 7. ReVISION-derived global area strain correlates with TomTec-derived EF These evaluations were performed in the following populations: A. The entire database (n=811) B. Clinical subpopulations in the database: 1. Heart failure patients (n=95) 2. Heart transplantation patients (n=86)	Pass

	3. Valvular heart disease patients (n=148) 4. Elite athletes (n=137) 5. Adult healthy controls (n=191) 6. Other adult cardiovascular disease patients (n=50) 7. Pediatric renal transplant patients (n=53) 8. Pediatric healthy controls (n=51) C. Age category subpopulations: 1. Child (2-12 years of age) (n=19) 2. Adolescent (12-18) (n=55) 3. Transitional adolescent (18-21) (n=79) 4. Adult (21+) (n=645) D. Subpopulations based on RV dysfunction present/absent: 1. RV dysfunction (n=107) 2. No RV dysfunction (n=704)	
cMRI Validation	Three (3) subjects with available retrospective Cardiac Magnetic Resonance Imaging (cMRI) were evaluated by ReVISION Software by calculating right ventricular (RV) volumes and ejection fraction (EF). Acceptance criteria for end-diastolic volume (EDV) was ±45 mL absolute difference. Acceptance criteria for end-systolic volume (ESV) was ±28 mL absolute difference. Acceptance criteria for ejection fraction (EF) was ±10 % absolute difference.	Pass
Usability Testing		
Usability Evaluation	15 participants completed a usability test focusing on the main elements of ReVISION Software workflow and use errors. Acceptable results found no further risks, hazards, or areas for immediate modification.	Pass

Clinical Testing Summary [807.92(b)(2)]:

No clinical testing was conducted on the Argus Cognitive ReVISION Software to support a determination of substantial equivalence to the predicate device.

CONCLUSIONS [807.92(b)(3)]

Completion of all verification and validation activities demonstrate that the subject device meets all design and performance requirements and is substantially equivalent to the predicate device.

Table 2: Substantial Equivalence Table

Feature	Predicate Device TomTec-Arena TTA2 4D RV (K150122)	Subject Device ReVISION Software (K223322)	Rationale for Substantial Equivalence
K-number	K150122	Not available	Subject of this submission is the ReVISION Software.
Regulation Number and Regulation Name	21CFR 892.2050; Medical image management and processing system	21CFR 892.2050; Medical image management and processing system	Identical to predicate device.
Classification Product Code	LLZ	LLZ	Identical to predicate device.
Class	2	2	Identical to predicate device.
Classification Panel	Radiology	Radiology	Identical to predicate device.
Device Description	TomTec-Arena TTA2 is a clinical software package for reviewing, quantifying and reporting digital medical data. The 4D RV-Function of the TomTec-Arena TTA2 software is a right ventricular (RV) quantification tool for routine clinical work, pulmonary hypertension, and right-sided heart failure. The application helps to overcome complexity of right-ventricle analysis by calculating standard values based on a semi-automatically generated 3D surface model.	The ReVISION Software assesses global and segmental function of the right ventricle (RV) of the heart via the decomposition of longitudinal, radial, and anteroposterior motions of the RV walls and quantifies their relative contribution to global RV ejection fraction along with longitudinal, circumferential and area strains using 3D datasets obtained by echocardiography.	Similar general device description to predicate device.
Indication for Use	Indications for use of TomTec-Arena software is the quantification and reporting of cardiovascular, fetal, and abdominal structures and function of patients with suspected disease to support the physicians in the diagnosis.	Indications for use of the Argus Cognitive ReVISION Software are quantification and reporting of right ventricle (RV) structures and function of patients (adults only) with suspected disease to support physicians' diagnosis.	A subset of the predicate device's intended use.
Site of Use	Hospitals, clinics and physician's offices.	Hospitals, clinics and physician's offices.	Identical to predicate device.
Application Description / Quantification Technology of RV	Software function provides a morphological and functional assessment of the right ventricle based on a surface model of the RV.	Software function provides a morphological and functional assessment of the right ventricle based on a surface model of the RV.	Identical to predicate device.
Intended User Group	TomTec-Arena is intended to be used only by licensed medical practitioners or assistant medical technicians.	The ReVISION Software is intended to be used only by licensed medical practitioners or assistant medical technicians.	Identical to predicate device.

Feature	Predicate Device TomTec-Arena TTA2 4D RV (K150122)	Subject Device ReVISION Software (K223322)	Rationale for Substantial Equivalence
Design	Software as a medical device	Software as a medical device	Identical to predicate device.
2D RV calculated parameters	• RVDd base (RVD1): Right Ventricle Distance base (mm) • RVDd mid (RVD2): Right Ventricle Distance medial (mm) • RVLd (RVD3): Right Ventricle Distance Longitudinal (mm) • TAPSE: Tricuspid annular plane systolic excursion (mm) • FAC: Fractional area change (%) • RVLS (free wall): right ventricular longitudinal strain (free wall) (%) • RVLS (Septum): right ventricular longitudinal strain (septum) (%) • Global strain • TAPSE: MMode measurement for movement of TV between ED and ES • RV distance measurements: 3 distance measurements in the RV A4C in ED. • RVD1: maximal short-axis dimension in the basal one third of the right ventricle • RVD2: distance is measured on 50% of RVLd (RVD3) and parallel to the RVD1 • RVD3: base–apex length	None	Only 3D parameters are calculated.
3D RV calculated parameters	• EDV: End-diastolic Volume • EDVI: End-diastolic Volume Index • ESV: End-systolic Volume • ESVI: End-systolic Volume Index • SV: Stroke Volume • EF: Ejection Fraction	• EDV: End-diastolic Volume • ESV: End-systolic Volume • SV: Stroke Volume • EF: Ejection Fraction	Following indexed values are not calculated: • EDVI: End-diastolic Volume Index • ESVI: End-systolic Volume Index. These values are raw ones divided by BSA (which can be calculated using the patient weight and height).

Feature	Predicate Device TomTec-Arena TTA2 4D RV (K150122)	Subject Device ReVISION Software (K223322)	Rationale for Substantial Equivalence
3D RV calculated parameters	• EF: Ejection Fraction • SV: Stroke Volume	• Longitudinal EF • Radial EF • Anteroposterior EF • Global and segmental longitudinal strain • Global and segmental circumferential strain • Global and segmental area strain	These are the novel measures that the ReVISION Software adds on top of TomTec-derived ones.
Export Formats	Beutel value export into .ucd, .ply or .obj formats	None	No 3D beutel export possibility. The predicate device's output (exported 3D beutel models in .ucd format) is the input for the Subject Device. The subject device analyzes these models in a more detailed manner and provides novel measures without altering the raw information contained by the predicate device's output. Thus, these novel features do not raise different questions of safety and effectiveness but support clinical decision making with additional information derived from the raw data.