



September 3, 2025

Arterys, Inc.
Bethany Barrett
Director, Regulatory Affairs
600 W. Chicago Ave., Suite 510
Chicago, Illinois 60654

Re: K252539

Trade/Device Name: Tempus Pixel
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: QIH, LLZ
Dated: August 11, 2025
Received: August 12, 2025

Dear Bethany Barrett:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink that reads "Jessica Lamb". The signature is written in a cursive style. Behind the signature, there is a large, light blue watermark of the letters "FDA".

Jessica Lamb, Ph.D.
Assistant Director
DHT8B: Division of Radiologic Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K252539

Device Name
Tempus Pixel

Indications for Use (Describe)

Tempus Pixel software is a medical diagnostic application that displays, processes, stores, and transfers DICOM and non-DICOM medical data. It provides the capability to store images and patient information, and perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers and on monitors/screens that meet appropriate technical specification for image diagnosis.

Tempus Pixel includes an optional Pixel Cardio module which is used to analyze the heart and its major vessels using multi-slice, multi-phase, and velocity-encoded cardiovascular magnetic resonance (MR) images. It provides clinically relevant and reproducible, quantitative data, and has been tested and validated on MR images acquired from both 1.5T and 3.0T MR Scanners.

Tempus Pixel includes an optional Pixel Therapy Response Evaluation module which provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy follow-up examinations. It is a tool used to support the oncological workflow by helping the user confirm the absence or presence of lesions, including evaluation, quantification, follow-up, and documentation of any such lesions.

Tempus Pixel software is intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary Tempus Pixel

Sponsor Name:	Arterys, Inc. 600 W Chicago Ave Ste #510, Chicago, IL 60654 Phone: (833) 514-4187
Contact Person:	Bethany Barrett Director, Regulatory Affairs Arterys, Inc. Phone: (800) 739-4137 bethany.barrett@tempus.com
Date Summary Prepared:	September 2, 2025
Device Trade Name:	Tempus Pixel
Common Name:	Medical image processing software
Classification Name:	Medical image management and processing system
Regulation Number:	21 CFR 892.2050
Product Code:	QIH, LLZ
Predicate Device:	Arterys MICA
Submission Number:	K203744
Product Code:	QIH, LLZ

Indications For Use

Tempus Pixel software is a medical diagnostic application that displays, processes, stores, and transfers DICOM and non-DICOM medical data. It provides the capability to store images and patient information, and perform filtering, digital manipulation, and quantitative measurements. The client software is designed to run on standard personal and business computers and on monitors/screens that meet appropriate technical specification for image diagnosis.

Tempus Pixel includes an optional Pixel Cardio module which is used to analyze the heart and its major vessels using multi-slice, multi-phase, and velocity-encoded cardiovascular magnetic resonance (MR) images. It provides clinically relevant and reproducible, quantitative data, and has been tested and validated on MR images acquired from both 1.5T and 3.0 T MR Scanners.

Tempus Pixel includes an optional Pixel Therapy Response Evaluation module which provides analytical tools to help the user assess and document changes in morphological activity at diagnostic and therapy



follow-up examinations. It is a tool used to support the oncological workflow by helping the user confirm the absence or presence of lesions, including evaluation, quantification, follow-up, and documentation of any such lesions.

Tempus Pixel software is intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis, but it does not directly generate any diagnosis or potential findings.

Device Description

Tempus Pixel is a dedicated software application for evaluating various DICOM modalities, including multi-slice and multi-phase computed tomography (CT), magnetic resonance (MR) images, ultrasound, x-ray, and mammography. Pre-existing images are uploaded into Tempus Pixel in a DICOM format from a PACS or a scanner. Tempus Pixel is completely hosted in the cloud and is accessed using a Google Chrome™ web browser by navigating to the following <https://app.arterys.com>. Cloud servers are provided by the Google Cloud Platform and service is accessible globally.

The Pixel application is designed around a modular architecture of separate components that make up a basic image viewer. These include the studylist, from which studies are selected and opened, the image display (2D, 3D, MIP, etc), view synchronization, metadata information, and various navigational, measurement, and other action tools.

Functionality provided by the Pixel application is extended by additional Cardio and Therapy Response Evaluation application modules which add support for specific clinical workflows. The Cardio module includes support for 4D flow studies and provides additional functionality specific to cardiac studies. The Therapy Response Evaluation module includes functionality specific to evaluating and measuring lesions.

The device also facilitates several FDA-cleared third party inference models. Each third party inference integration implements a set of filters that determine whether a given study or workflow is eligible to be submitted to the third-party inference model. If eligible, a request is queued and processed by the third party model. Results are returned to Pixel from the third party model and are stored in the study collection.

The clinician retains the ultimate responsibility for making the pertinent diagnosis based on their standard practices and visual comparison of images. Tempus Pixel software is a complement to these standard procedures.

Intended Use

Tempus Pixel is Intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis.

Intended Patient Population

Pediatric (neonate, infant, child and adolescent) and adult populations. For Pixel Lung only, the lung detection module is intended for the asymptomatic patient population 18 years of age and older.

Comparison of Technological Characteristics

The subject device has similar technological characteristics as the predicate device, with only minor differences in T1/T2 quantification/mapping functionality and minor incremental updates to existing software features for user experience improvements. The added inline map generation feature employs the same process and calculations used for the predicate device's T1 and T2 ROI quantification features. The minor technological differences do not raise different questions of safety or effectiveness.

Table 1. Comparison of Key Technological Characteristics

Characteristic	Predicate Device (Arterys MICA K203744)	Subject Device (Tempus Pixel)
Intended Use	Intended to be used as a support tool by trained healthcare professionals to aid in diagnosis. It is intended to provide image and related information that is interpreted by a trained professional to render findings and/or diagnosis.	Same
Intended Patient Population	Pediatric (neonate, infant, child and adolescent) and adult populations. For Pixel Lung only, the lung detection module is intended for the asymptomatic patient population 18 years of age and older.	Same
Rx / OTC	Rx Only	Same
Type of scans	Viewer/Pixel: Supported DICOM modalities Cardio: MR Onco/Therapy Response Evaluation: MR and CT	Same
Image upload and storage	Yes. DICOMweb and legacy upload methods. JPEG and JPEG 2000 image compression.	Same
Studylist with filter and searching	Yes	Same
Image display and layouts	Yes, including 2D, 3D, MIP, MPR display and numerous layout options.	Same
Image navigation tools	Pan, zoom, rotate, slice/time scroll, W/L, slab thickness, cine, flow direction, flip, W/L invert & presets.	Same
View DICOM metadata	Patient, study, orientation, and pixel information.	Same
Measuring tools	Yes - linear, area, and volume.	Same
Display results of AI models	Arterys and 3rd party AI models.	Same
Reporting	All modules. Secondary captures. Dictation integration.	Same
Cardiac views	Yes - automatically identified + user editable	Same

Characteristic	Predicate Device (Arterys MICA K203744)	Subject Device (Tempus Pixel)
Ventricular function	For short-axis stack. Automatically identified + user editable.	Same
Cardio visualization and quantification	Yes. 2D phase contrast, 4D flow, perfusion, delayed enhancement, T1, T2, and T2* workflows. Editable flow correction mask using ML model.	Same
T1 and T2	For T1, the contouring of the LV Endo and LV Epi can be obtained automatically using a deep learning model or can be drawn manually by the user. For T2, the user can manually contour the myocardium structures using the same tools. Each step of the workflow for each of these features can be reviewed and edited by the user. T1 and T2 maps are limited to user-defined regions of interest (ROIs) within the myocardium and the left ventricle blood pool on the original (raw) T1 and T2 series.	For T1, the contouring of the LV Endo and LV Epi can be obtained automatically using a deep learning model or can be drawn manually by the user. For T2, the user can manually contour the myocardium structures using the same tools. Each step of the workflow for each of these features can be reviewed and edited by the user. Full device-generated T1 and T2 inline map functionality. One generated inline map is produced for each slice of the raw input series.
Cardio reporting	Yes, with numerous content configurations by user.	Same
Oncology nodule modification	Yes, with editing, creating, deleting, with sorting options for list of nodules.	Same
Oncology longitudinal tracking	Yes, with a graphical display. Improved workflow and linking.	Same
Oncology reporting - Lung-RADS	Yes	Same
Machine-based learning models	Locked/Static	Same

Summary of Non-Clinical Studies

The performance of modified Tempus Pixel device was evaluated based on non-clinical testing, as follows:

- T1/T2 inline mapping features were validated by comparing outputs to those generated from commercially available MR scanners. All acceptance criteria was met.
- Software Verification and Validation (V&V): SW V&V activities were completed and all Unit Tests, Integration Tests, and System Tests met the acceptance criteria.
- Human Factors/Design Validation Assessment: Testers with suitable clinical/product knowledge executed validation testing to ensure that the documented User Needs were satisfied.
- Cybersecurity Testing: Cybersecurity activities were completed and associated risks have been appropriately mitigated.

Table 2 below summarizes methods and results for the T1/T2 inline map validation, human factors assessment, and software verification testing.

Table 2. Summary of Non-Clinical Studies - Methods and Results

Test	Summary of Methods	Acceptance Criteria	Results
T1/T2 Inline Map Validation	<p>Validation was performed by comparing the Tempus Pixel generated inline maps to maps generated from FDA-cleared MR scanners using the same input series. For each test series, the Pixel inline map was compared to the MR scanner generated inline map by placing a minimum of four regions of interest (ROI) on different parts of the myocardium.</p> <p><u>Sample Size:</u> T1: 30 series spread evenly across manufacturer and scanner type. There were 4 ROIs assessed per series, resulting in a total of 120 ROIs for T1.</p> <p>T2: 30 series spread evenly across manufacturer and scanner type. There were 4 ROIs assessed per series, resulting in a total of 120 ROIs for T2.</p> <p>FDA-cleared scanners used for comparison included:</p> <p><u>GE 1.5T</u> Signa HDxt, SIGNA Artist, SIGNA Voyager, Optima MR450</p> <p><u>GE 3T</u> SIGNA Premier, DISCOVERY MR750w, SIGNA Pioneer</p> <p><u>Philips 1.5T</u> Ingenia Ambition X, Achieva</p> <p><u>Philips 3T</u> Ingenia Elition X, Ingenia</p> <p><u>Siemens 1.5T</u> MAGNETOM Sola, MAGNETOM Aera</p> <p><u>Siemens 3T</u> MAGNETOM Vida, MAGNETOM Skyra</p>	<p>T1: The 95th percentile deviation (absolute error) between the Tempus Pixel inline maps and scanner generated inline maps, as assessed across means from all 120 ROIs, must be within the range from -30ms to +30ms. All measurements must be within 1.5 times this range (-45ms to +45ms).</p> <p>T2: The 95th percentile deviation (absolute error) between the Tempus Pixel inline maps and scanner generated inline maps, as assessed across means from all 120 ROIs, must be within the range from -3ms to +3ms. All measurements must be within 1.5 times this range (-4.5ms to +4.5ms).</p>	<p>T1: Across all 120 ROIs</p> <ul style="list-style-type: none"> ● Mean absolute error = 4.76 ms ● 95th percentile absolute error = 13.82 ms ● Max absolute error = 28.57 ms <p>PASS</p> <p>T2: Across all 120 ROIs</p> <ul style="list-style-type: none"> ● Mean absolute error = 0.85 ms ● 95th percentile absolute error = 2.48 ms ● Max absolute error = 2.97 ms <p>PASS</p>

Test	Summary of Methods	Acceptance Criteria	Results
Human Factors/Design Validation	<p>The Pixel user interface remains largely identical for the new T1/T2 inline mapping as compared to that for T1/T2 ROI mapping in the predicate device. As a conservative measure, a limited-scope external validation of T1 and T2 inline map generation was conducted by three physicians experienced in assessing and quantifying parametric mapping data within Pixel Cardio software. The physicians were instructed to open studies, find automatically generated inline maps, create new inline maps and locate them in the series list.</p>	<ul style="list-style-type: none"> • When a study with a parametric mapping raw data series (T1/T2) is opened, there will automatically be an inline map generated by Tempus located in the series list within the study. • When the user loads a parametric mapping raw data series into the viewer and opens the corresponding module, they will have the option to generate a new inline map. • When the user generates a new inline map, the inline map will populate within the series list and will have a distinct series description. • Users are able to quantify T1/T2 values from the Pixel generated inline map and verify these values against expected anatomical/ pathological findings. 	<p>PASS. No deviations or unexpected Results.</p>
Software Verification	<p>Software unit and system verification testing for the T1/T2 inline mapping was performed in accordance with Arterys software design control procedures.</p>	<p>All test cases were required to meet pre-established expected software outputs.</p>	<p>PASS. All testing passed and no new anomalies were identified.</p>



Summary of Clinical Studies

No clinical studies were performed for the modified Tempus Pixel device. Clinical reference data, in the form of image series acquired from commercially available FDA-cleared MR scanners, were used for validation of the new T1 and T2 inline mapping functionality.

Substantial Equivalence Conclusions

The indications for use and intended use of the subject and predicate devices are the same. Both are imaging software intended to be used as a support tool by trained healthcare professionals to aid in diagnosis.

The results of the substantial equivalence assessment, taken together with software testing and non-clinical studies, demonstrate that the Tempus Pixel device with the modifications described in this premarket notification does not raise different questions of substantial equivalence when compared to the predicate device. The device performs as intended and has performance characteristics that are substantially equivalent to the Arterys MICA predicate device cleared per K203744.