



March 27, 2026

Artiness s.r.l.
% Monica R. Montanez
Principal Strategy Consultant
NAMSA
6750 Wales Road
Toledo, OH 43619

Re: K252195

Trade/Device Name: ARTICOR planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 2, 2026
Received: March 3, 2026

Dear Monica R. Montanez:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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 faint, light blue watermark of the letters "FDA".

Jessica Lamb, PhD

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.

K252195

?

Please provide the device trade name(s).

?

ARTICOR planner

Please provide your Indications for Use below.

?

ARTICOR planner is intended for use as a software interface and image segmentation system to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, ARTICOR planner provides additional visualization and measurement tools to enable the user to screen and plan the procedure.

ARTICOR planner should be used in conjunction with other diagnostic tools and expert clinical judgement.

Please select the types of uses (select one or both, as applicable).

- Prescription Use (Part 21 CFR 801 Subpart D)
 Over-The-Counter Use (21 CFR 801 Subpart C)

?

510(k) Summary

ARTICOR planner

K252195

1. Submission Sponsor

Artiness s.r.l.

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Milan

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2. Submission Correspondent

NAMSA

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Contact: Monica R. MONTANEZ

Title: Principal Strategy Consultant

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3. Date Prepared

06-Feb-2026

4. Device Identification

Trade/Proprietary Name: ARTICOR® planner

Common/Usual Name: Medical image management and processing system

Classification Name: System, Image Processing, Radiological

Regulation Number: 892.2050
Product Code: LLZ, System, Image Processing, Radiological
Device Class: Class II
Classification Panel: Radiology

5. Legally Marketed Predicate Device

K190874, Device: Materialise Mimics Enlight, Manufacturer: Materialise N.V.

6. Indications for Use Statement

ARTICOR planner is intended for use as a software interface and image segmentation system to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, ARTICOR planner provides additional visualization and measurement tools to enable the user to screen and plan the procedure.

ARTICOR planner should be used in conjunction with other diagnostic tools and expert clinical judgement.

7. Device Description

ARTICOR planner is a software interface that enables the user to plan structural heart and vascular procedures through the following phases:

1. Analyze anatomy
2. Plan device
3. Plan delivery
4. Output

The user can create and optimize 3D reconstruction of the patient's anatomy based on DICOM-compliant medical images using a variety of manual and semi-automatic segmentation tools available in a desktop software. These models, and the images from which they are created, can then be used, in an Augmented Reality (AR) environment that communicates with the desktop software through cloud services, to conduct measurements and plan the treatment. In particular, the user can evaluate the sizing and positioning of structural heart and vascular devices and prepare the fluoroscopy angles for the procedure.

8. Predicate Device Comparison

The following table compares the ARTICOR planner to the predicate device with respect to indications for use, principles of operation, technological characteristics, and performance testing. The comparison of the devices provides more detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the predicate device.

Table: Comparison of Characteristics

Manufacturer	Artiness s.r.l.	Materialise N.V.	Device Comparison
Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
510(k) Number	K252195	K190874	Not applicable
Product Code	LLZ	LLZ	Same
Regulation Number	892.2050	892.2050	Same
Regulation Name	Medical image management and processing system	Medical image management and processing system	Same
Indications for Use	<p>ARTICOR planner is intended for use as a software interface and image segmentation system to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, ARTICOR planner provides additional visualization and measurement tools to enable the user to screen and plan the procedure.</p> <p>ARTICOR planner should be used in conjunction with other diagnostic tools and expert clinical judgement.</p>	<p>Materialise Mimics Enlight is intended for use as a software interface and image segmentation system for the transfer of DICOM imaging information from a medical scanner to an output file.</p> <p>It is also intended as a software to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, Materialise Mimics Enlight provides additional visualization and measurement tools to enable the user to screen and plan the procedure.</p> <p>The Materialise Mimics Enlight output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of cardiovascular applications.</p> <p>Materialise Mimics Enlight should be used in conjunction with other diagnostic tools and expert clinical judgement.</p>	<p>Similar; the indications for use comparing ARTICOR planner and Materialise Mimics Enlight are similar. The predicate device can also produce output files whereas physical replicas of the planned device can be made through additive manufacturing. This does not raise any additional questions of safety or efficacy.</p>
Intended User Profile	Qualified healthcare professionals like surgeons, cardiologists, radiologists, physicians.	The user is a medical professional, like cardiologists, radiologists or clinical specialists.	Same
Intended Patient Population	The device is a software intended to be used on DICOM compliant medical images acquired on patients	The device is a software intended to be used on DICOM compliant medical images acquired on patients	Same

Manufacturer	Artiness s.r.l.	Materialise N.V.	Device Comparison
Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
	referred to structural heart and vascular procedures.	referred to structural heart and vascular procedures.	
Device Description	<p>ARTICOR planner is a software interface that enables the user to plan structural heart and vascular procedures through the following phases:</p> <ol style="list-style-type: none"> 1. Analyze anatomy 2. Plan device 3. Plan delivery 4. Output <p>The user can create and optimize 3D reconstruction of the patient's anatomy based on DICOM-compliant medical images using a variety of manual and semi-automatic segmentation tools available in a desktop software. These models, and the images from which they are created, can then be used, in an augmented reality software that communicates with the desktop software through cloud services, to conduct measurements and plan the treatment. In particular, the user can evaluate the sizing and positioning of structural heart and vascular devices and prepare the fluoroscopy angles for the procedure.</p>	<p>Materialise Mimics Enlight for structural heart and vascular planning is a software interface that is organized in a workflow approach. High level, each workflow in the field of structural heart and vascular will follow the same kind of structure of 4 steps which will enable the user to plan the procedure:</p> <ol style="list-style-type: none"> 1. Analyse anatomy 2. Plan device 3. Plan delivery 4. Output <p>To perform these steps the software provides different methods and tools to visualize and measure based on the medical images. The user is a medical professional, like cardiologists, radiologists or clinical specialists. To start the workflow DICOM compliant medical images will need to be imported. The software will read the images and convert them into a project file. The user can now start the workflow and follow the steps visualized in the software. The base of the workflow is to create a 3D reconstruction of the anatomy based on the medical images to use this further together with the 2D medical images in the workflow to plan the procedure.</p>	<p>Similar; the predicate device Materialise Mimics Enlight functionality is organized as a guided workflow with different steps where the relevant information to plan the procedure is produced and assessed by the user at each step, while in the subject device the workflow is not guided. There are no additional questions of safety or efficacy as the product requirements are met.</p>
Prescription or OTC	Prescription	Prescription	Same

Manufacturer	Artiness s.r.l.	Materialise N.V.	Device Comparison
Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
Hardware	PC and head-mounted display: ARTICOR planner comprises a desktop software running on a PC and an augmented reality software running on a HMD; the two communicates through cloud-hosted services.	PC: Materialise Mimics Enlight consists of a desktop software running on a PC.	Different; the subject device includes option to run on a commercial head mounted display and allows to plan patient's treatment in an augmented reality environment. Usability of the head mounted display software and performances of the measurement function implemented in it have been evaluated through usability tests and performance bench tests respectively, showing that the technological difference between predicate and subject device does not hinder safety and effectiveness. In addition, display quality tests have been executed as per IEC 63145 on the head mounted display with satisfactory results for the intended use of the subject device. Finally, there are other cleared devices with head mounted display options (including the reference device Elucis K220649), so this does not raise any additional questions of safety or efficacy.
Imaging Modality	CT	CT	Same
Input Data Type Supported	DICOM compliant medical images OBJ/STL	DICOM compliant medical images STL that needs to be checked by Materialise team so to validate the algorithms for the device	Same
Software Organization	Functionality is not organized as a guided workflow.	Functionality is organized as a guided workflow.	Different; the subject device shares the same functionalities of the predicate device without a guided workflow. There are no additional questions of safety or efficacy as the product requirements are met.
Image Viewing	View medical images in a variety of planar and volumetric reformations	View medical images in a variety of planar and volumetric reformations	Same

Manufacturer	Artiness s.r.l.	Materialise N.V.	Device Comparison
Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
3D patient-specific models creation	Create 3D models from medical images using a variety of common modeling tools. Review and edit existing 3D models.	Either automatic or semi-automatic segmentation. Semi-automatic segmentation is done through placing two points on each structure of interest.	Similar; the ability to complete semi-automatic segmentation does not have an impact on the operation or function of the device raising no additional questions of safety or efficacy.
Multi-phases images	Advanced modeling algorithms enable dynamic segmentation of multi-phase (4D) images	Possibility to tag and switch between cardiac phases to gain more 4D insight from being able to work with multi-phase data	Similar; the end result is the same for both the subject device and predicate device, though the process is slightly different. There are no additional questions of safety or efficacy raised.
Planning	ARTICOR planner is an augmented reality software, which allows the clinician to prepare a plan for a structural heart or vascular procedures based on: <ul style="list-style-type: none"> - DICOM images - 3D models of anatomy and devices - landmarks - measurements performed on the aforementioned objects. 	Mimics Enlight is intended as a software to aid in reading and interpreting DICOM compliant images for structural heart and vascular treatment options. For this purpose, Materialise Mimics Enlight provides visualization and measurement tools to enable the user to screen and plan the procedure.	Same
Measurements	Perform measurements on images and models on an head-mounted display in augmented reality environment	The software provides different methods and tools to visualize and measure based on the medical images. Measurement tools are either automated or manual. Measurements are performed on PC monitors.	Similar, the same type of measurements can be performed. The only difference is that the subject device offers the possibility to perform measurements only on augmented reality head-mounted displays, while the predicate device is a software to be executed on a PC. Usability of the head mounted display software and performances of the measurement function implemented in it have been evaluated through usability tests and performance bench tests respectively, showing that the technological difference between predicate and subject device does not hinder safety and

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Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
			effectiveness. In particular, measurements accuracy and reproducibility results were obtained by executing tests on the headset using as reference the measurements obtained with an FDA-cleared DICOM viewer on a conventional PC monitor. Moreover, the identified reference device is cleared for market which also includes ability to perform measurements on images and models in virtual reality.
Device Planning	Plan treatments using 3D models (both anatomical models derived from medical images and models derived from files describing the geometry of planning objects) and medical images.	Device delivery simulation provides an understanding of device feasibility and implant fit.	Similar; the planning process is similar allowing the same function and operation for the healthcare professional to formulate treatment plans and assist in surgical planning. Validation of the software application is done for the planning activities, therefore no additional questions are raised for safety or efficacy.
Landmarks	Possibility to place or compute landmarks on models in the augmented reality (AR) environment	Possibility to place or compute landmarks on the CT or directly on the interactive 3D model	Similar; the operation of placing landmarks only differs also being able to conduct this in an AR environment which is not available with the predicate device. There are no additional questions of safety or efficacy.
Delivery pathway assessment	Possibility to define a delivery pathway (spline) by selecting reference points in the augmented reality environment.	For TMVR plan for transeptal or transapical delivery viewing surrounding anatomy and visualization of potential fossa ovalis puncture locations.	Similar; the operation of determining delivery pathway differs in the process for how this is done by each application and being able to conduct this in an AR environment. There are no additional questions of safety or efficacy.
Fluoroscopic angles for procedure	Fluoroscopic simulation with possibility for the user to look for optimal projection angles	Fluoroscopic simulation with possibility for the user to look for optimal projection angles	Same. Accuracy results were obtained by executing tests on the headset using as reference the fluoroscopic projection angles obtained with an FDA-cleared DICOM

Manufacturer	Artiness s.r.l.	Materialise N.V.	Device Comparison
Trade Name	ARTICOR® planner	Materialise Mimics Enlight	
			viewer on a conventional PC monitor.
Save of surgical planning	Save images, measurements, 3D models, and other treatment planning information for later review	Save images, measurements, 3D models, and other treatment planning information in a PowerPoint report for later review	Same
Processing to output file	Not available	The device generates an output file that can be used for the fabrication of physical replicas	Different; the predicate device generates an output file that can be used for the fabrication of physical replicas, the subject device does not have such a functionality. There is no impact to safety or efficacy offering this feature by the predicate device.
Remote collaboration	Support for collaboration between multiple remote users in the accompanying augmented reality (AR) environment	Not available	Different; remote collaboration is enabled on the subject device offering support for collaboration between multiple remote users in the augmented reality environment. Collaborative sessions are available on other cleared devices and does not raise any additional questions or safety or efficacy.

9. Non-Clinical Performance Data

As part of demonstrating safety and effectiveness of ARTICOR planner and in showing substantial equivalence to the predicate device that are subject to this 510(k) submission, Artiness s.r.l. completed a number of non-clinical performance tests. Testing addressed software functionality, image segmentation, visualization, interoperability with head-mounted displays (HMD), optical quality testing of HMD, augmented reality (AR) measurement accuracy and reproducibility, fluoroscopic planning accuracy, and usability. All testing was performed according to internal verification and validation procedures compliant with IEC 62304, international standards and/or applicable FDA guidance documents:

- Software verification and validation conducted across the full software life cycle in accordance with internal procedures aligned with IEC 62304 and FDA guidance “Content of Premarket Submissions for Device Software Functions” confirmed that the finished product meets its predefined requirements. Verification confirmed correct implementation of core

functions, including DICOM import, segmentation, 3D model generation, visualization, measurement tools, and AR rendering.

- Interoperability between ARTICOR planner and the HMD Microsoft HoloLens 2 was confirmed through operational use testing, software verification testing of the AR application, accuracy and reproducibility testing of measurements and fluoroscopic projection angles in the augmented reality environment and usability tests performed by multiple intended users with the HMD.
- Display quality of the HMD: since ARTICOR planner supports visualization on a commercial HMD in addition to conventional monitors, the display quality of the HMD was characterized by an ISO/IEC 17025–accredited laboratory according to IEC 63145 and IDMS standards. Testing included luminance and luminance uniformity, gamma behavior, Michelson contrast, spectral transmittance, field of view, distortion, and qualitative visual assessment using TG270-sQC patterns. The HMD display performance was found suitable for the intended use of ARTICOR planner, which is a non-diagnostic, pre-operative planning use.
- Augmented reality environment use for acquisition of measurements: bench performance testing was conducted based on FDA guidance “Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions” to evaluate the accuracy and reproducibility of manual measurements performed in the AR environment of ARTICOR planner. Accuracy was assessed by comparing measurements obtained using ARTICOR planner on the HMD with measurements obtained using the FDA-cleared DICOM viewer OsiriX MD (K101342) on a conventional PC monitor. Reproducibility was assessed by comparing measurements performed by different operators using ARTICOR planner. Multiple cardiovascular anatomic structures were evaluated using representative CT datasets. Statistical analyses compared ARTICOR planner results to the reference system and between operators. Results showed all measurement biases well below the 5% predefined acceptance criteria, correlation coefficients ≥ 0.9 between operators, and no statistically significant differences ($p > 0.05$). These results demonstrate that ARTICOR planner provides accurate and reproducible measurements in the AR environment.
- Augmented reality environment for planning of fluoroscopic projection angles: bench performance testing was conducted based on FDA guidance “Technical Performance Assessment of Quantitative Imaging in Radiological Device Premarket Submissions” to evaluate the accuracy of fluoroscopic projection angles planned in the AR environment of ARTICOR planner. Projection angles obtained with ARTICOR planner on the HMD were compared with angles obtained using the FDA-cleared device OsiriX MD (K101342) on a conventional PC monitor. Multiple fluoroscopic views were evaluated on a representative synthetic dataset. Results showed that all projection angle biases were well below the 5° predefined acceptance criteria, correlation coefficients ≥ 0.9 , and no statistically significant differences ($p > 0.05$). These results demonstrate that ARTICOR planner enables accurate fluoroscopic projection planning in the AR environment.
- Usability testing was conducted according to a human factors engineering protocol aligned with IEC 62366 principles and FDA guidance “Applying Human Factors and Usability Engineering to Medical Devices”. Representative intended users (e.g., clinicians) performed predefined planning and measurement tasks in simulated use environments using

ARTICOR planner. Participants received training consistent with intended use. Tasks included loading datasets, interacting with 3D models, performing measurements, and planning views in the AR environment. Across participants, 94% of tasks were completed successfully, 5% resulted in close calls, and 1% were classified as failures. All failures were analyzed and determined not to impact safety or device effectiveness. Risk analysis confirmed that identified usability risks were adequately controlled and no residual usability risks remain that would affect safe and effective use of ARTICOR planner.

10. Clinical Performance Data

There was no human clinical testing required to support the substantial equivalence of the subject device. The non-clinical testing detailed in this submission supports the substantial equivalence of the device.

11. Statement of Substantial Equivalence

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device. Based on the comparison and analysis above, the ARTICOR planner is determined to be substantially equivalent to the referenced predicate device.

12. Revision History

Rev.	Description
00	First emission
01	<p>Updated date the summary was prepared.</p> <p>Clarified that measurements can be performed only on AR HMD in the subject device, while on PC in the predicate device and that measurements accuracy and reproducibility results were obtained by executing tests on the headset using as reference the measurements obtained with an FDA-cleared DICOM viewer on a conventional PC monitor.</p> <p>Added information that fluoroscopic projection angles accuracy results were obtained by executing tests on the headset using as reference the projection angles obtained with an FDA-cleared DICOM viewer on a conventional PC monitor.</p> <p>Added reference to display quality tests performed on the headset.</p> <p>Added details and reorganized content of section 9 "Non-Clinical Performance Data"</p>