Materialise N.V.
Victoria Becheva
Regulatory Affairs Specialist
Technologielaan 15
Leuven, 3001
BELGIUM

February 12, 2024

Re: K233217
Trade/Device Name: Mimics Cardiac Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: January 12, 2024
Received: January 12, 2024

Dear Victoria Becheva:

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.

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,

Jessica Lamb, Ph.D.
Assistant Director
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233217

Device Name
Mimics Cardiac Planner

Indications for Use *(Describe)*
Mimics Cardiac Planner is intended to be used as a pre-procedural planning software to screen and plan structural heart and vascular procedures based on DICOM compliant medical images. Mimics Cardiac Planner allows the clinician to visualize, measure, annotate and edit pre-procedural plan data. The software can be used to evaluate the sizing, positioning and delivery pathway of structural heart and vascular devices.
Mimics Cardiac Planner should be used in conjunction with other diagnostic tools and expert clinical judgement.

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.

K233217 510(k) Summary

The following section is included as required by the Safe Medical Devices Act (SMDA) of 1990 and 21CFR 807.92.

Company name	Materialise N.V.
Establishment registration number	3003998208
Street Address	Technologielaan 15
City	Leuven
Postal code	3001
Country	Belgium
Phone number	+32 16 39 66 11
Fax number	+32 16 39 66 06
Principal Contact person	Victoria Becheva
Contact title	Regulatory Affairs Specialist
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Jenny Jones
Contact title	Global Quality & Regulatory Manager, Medical
Contact e-mail address	jenny.jones@materialise.com

Submission date

The date of the Traditional 510(k) submission is September 25, 2023.

Submission information

Trade Name	Mimics Cardiac Planner
Common Name	Image processing system
Classification Name	System, Image processing, Radiological
Regulation	21 CFR 892.2050 (Medical image management and processing system)
Product code	LLZ

Indications for Use

Mimics Cardiac Planner is intended to be used as a pre-procedural planning software to screen and plan structural heart and vascular procedures based on DICOM compliant medical images. Mimics Cardiac Planner allows the

clinician to visualize, measure, annotate and edit pre-procedural plan data. The software can be used to evaluate the sizing, positioning and delivery pathway of structural heart and vascular devices.

Mimics Cardiac Planner should be used in conjunction with other diagnostic tools and expert clinical judgement.

Description and functioning of the device

The Mimics Cardiac Planner is an online planning software, which allows the clinician to review and adjust a plan for a structural heart or vascular procedures based on DICOM images, 3D models and landmarks. The software guides the clinician through different steps of the cardio-vascular workflow, where the relevant information, like 3D models of anatomy and devices, images, landmarks and measurements are presented.

The software enables the clinician to review the anatomy and relevant workflow specific predefined set of measurements, evaluate the device size and position, assess the delivery pathway and prepare the fluoroscopy angles for the procedure.

The software provides the tools to adjust all predefined measurements, and to perform custom measurements.

The software is integrated with a Medical Device Data System, which is responsible for the case management and user management.

Predicate Devices

The **primary predicate device** to which substantial equivalence is claimed:

Trade or proprietary or model name	Mimics Enlight
510(k) number	K190874
Decision date	06/05/2019
Classification product code	LLZ
Manufacturer	Materialise N.V.

The **reference** *device*:

Trade or proprietary or model name	SurgiCase Shoulder Planner
510(k) number	K220452
Decision date	08/17/2022

Classification product code	QHE, KWS, PHX
Manufacturer	Materialise N.V.

Technological Characteristics

Comparison of technological characteristics with the **predicate device (Mimics Enlight, K190874)**.

The subject device Mimics Cardiac Planner employs similar fundamental technologies as Mimics Enlight.

Technological similarities include:

- *Device Functionality:* Both subject and predicate devices consist of a workflow to plan structural heart and vascular procedures which follows the same structure of steps which enable the user to plan the procedure:
    - Analyze anatomy
    - Plan device
    - Plan delivery
    - Output

  To perform these steps the software provides similar methods and tools to visualize, and measure based on the medical images and 3D models.
- *Virtual 3D models used during planning:* The geometric accuracy of the virtual models used in the subject device is the same as in the predicate device.
- *Software technology:* Both subject and predicate device are developed using the same underlying Materialise C++ code libraries.
- *Device design and development process:* Both predicate and subject device software are manufactured by the same company (Materialise NV), the subject device follows the same development cycle and testing procedures as the predicate device. The verification and validation of predicate and subject device has been done following the same procedures and workflows.

The following technological differences exist between the subject device and the predicate device:

- *Device Functionality:* Both devices require medical images as input. However, the predicate device provides segmentation and landmarking tools to create 3D models and landmarks, while the subject device also requires the input of 3D models and landmarks which is generated through a service delivered by Materialise.
- *Software technology:* while the predicate device is a desktop Windows software which is run locally on a computer of the clinician, the subject device is cloud software integrated with a medical device data system.

Comparison of technological characteristics with the **reference device (SurgiCase Shoulder Planner,** K**220452)**

The subject device Mimics Cardiac Planner employs similar fundamental technologies as SurgiCase Shoulder

Planner. Technological similarities include:

- *Device functionality:* much of the software functionality is shared between the subject and reference device, such as visualization of 3D models, images visualization, measurement tools, handling device libraries, positioning devices.
- *Process in which the software is used:* The input for both devices is uploaded on Medical Device Data system where segmentation and landmarking is performed through a service delivered by Materialise.
- *Software* technology: both devices are based on the same cloud technology and are integrated with the same Medical Device Data System.

The following technological differences exist between the subject device and the reference device:

- *Device functionality:* While from a feature perspective the tools in the software are very similar, they are applied to a different field (Cardiac vs Orthopedic). Additionally, the reference device generates a pre-surgical plan data file which can be used as input data to design shoulder guides and models, while the subject device does not currently generate such output.

Following the comparison between the subject and predicate device, and between subject and reference device, it can be concluded that the abovementioned technological differences between the subject and predicate device do not impact the safety and effectiveness of the subject device for the proposed indications for use as they are covered using a reference device with matching characteristics in the areas where the subject device differs from the predicate, as well as by verification and validation.

Performance Data

Software verification and validation were performed, and documentation was provided following the FDA guidance "Content of Premarket Submissions for Device Software Functions." This includes verification against defined requirements, and validation against user needs.

Summary

The characteristics that determine the functionality and performance of the subject device Mimics Cardiac Planner is substantially equivalent to the device cleared under Mimics Enlight (K190874), the primary predicate device. The non-clinical performance testing indicates that the subject device is as safe and effective as the predicate device. Therefore, it can be concluded that the Mimics Cardiac Planner is substantially equivalent to the predicate device.