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

March 12, 2026

Re: K251964
Trade/Device Name: Mimics Thoracic Planner
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: February 12, 2026
Received: February 13, 2026

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 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,

Jessica Lamb
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K251964

Device Name

Mimics Thoracic Planner

Indications for Use *(Describe)*

The Mimics Thoracic Planner is intended to be used as a pre-procedural planning software to review, analyze and plan pulmonary or thoracic procedures based on DICOM-compliant medical images.
The Mimics Thoracic Planner allows the clinician to visualize, measure and annotate pre-procedural plan data before and during the procedure, and perform post-op analysis.
The Mimics Thoracic Planner allows the clinician to edit pre-procedural plan data before the procedure.
The Mimics Thoracic 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K251964 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 12 March 2026.

Submission information

Trade Name	Mimics Thoracic 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

Description and functioning of the device

The *Mimics Thoracic Planner* is intended to be used as a pre-procedural planning software to review, analyze and plan pulmonary or thoracic procedures based on DICOM compliant medical images. The *Mimics Thoracic Planner* allows the clinician to visualize, measure and annotate pre-procedural plan data before and during the procedure, and perform post-op analysis. The *Mimics Thoracic Planner* allows the clinician to edit pre-procedural plan data before the procedure. The *Mimics Thoracic Planner* should be used in conjunction with other diagnostic tools and expert clinical judgement. The *Mimics Thoracic Planner* is an online planning software, which allows the clinician to review and adjust a plan for a surgical procedure of the pulmonary/thoracic anatomy based on DICOM images and 3D models. The planned procedure may be one of the following: segmentectomy, lobectomy, pneumectomy, etc. The *Mimics Thoracic Planner* software guides the clinician through different steps of the workflow, where the relevant information, like virtual 3D models of anatomy, images and measurements are presented. The software enables the clinician to review the anatomy, evaluate the target lesion, define the resection and assess the pathway to remove the resection. 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 case management and user management.

During the procedure, the intra-op step should only be used to visualize the pre-operative plan. *Mimics Thoracic Planner* is not intended to be used to modify the pre-operative plan during surgery.

Predicate Devices

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

Trade or proprietary or model name	Mimics Medical
510(k) number	K183105
Decision date	27 March 2019
Classification product code	LLZ
Manufacturer	Materialise N.V.

The **reference** *device*:

Trade or proprietary or model name	Mimics Cardiac Planner
510(k) number	K233217
Decision date	12 February 2024
Classification product code	LLZ
Manufacturer	Materialise N.V.

Indications for Use

The Mimics Thoracic Planner is intended to be used as a pre-procedural planning software to review, analyze and plan pulmonary or thoracic procedures based on DICOM compliant medical images.

The Mimics Thoracic Planner allows the clinician to visualize, measure and annotate pre-procedural plan data before and during the procedure, and perform post-op analysis.

The Mimics Thoracic Planner allows the clinician to edit pre-procedural plan data before the procedure.

Technological Characteristics

Comparison if technological characteristics with the primary predicate device **(Mimics Medical K183105)**

The subject device Mimics Thoracic Planner employs similar fundamental technologies as Mimics Medical.

The similarities include:

- *Indications for Use*
  Both the predicate and the subject device are intended to be used as planning software using medical images as input. Both devices are intended to perform measurements. Both devices are intended to be used in conjunction with other diagnostic tools and expert clinical judgement.

- *Device Functionality*
  Both the subject and primary predicate devices include tools for visualizing and measuring based on medical images and 3D models. These tools enable the user to analyze the anatomy, plan the procedure, and use the output file as a reference during the intervention.

- *Virtual 3D models used during planning*
  As such the geometric accuracy of the virtual models used in the subject device is the same as in the primary predicate device.

- *Software technology*
  Both subject and primary predicate device are developed using the same underlying Materialise technology.

- *Device design and development process*
  Both primary 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 primary predicate device. The verification and validation of primary predicate and subject device has been done following the same procedures and workflows.

- *Process in which the software is used*
  In a generic planning process, both devices can be used by medical professionals to plan treatment options.

- *Testing*
  Both the predicate device and subject device have undergone quantitative and qualitative testing of the system.

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

- *Indications for use*
  The indications for use of the subject device are a subset of the indications for use of the primary predicate device.

- *Device Functionality*
  While the primary predicate device requires medical images as input and will provide segmentation tools to create 3D models based on the medical images, the subject device is scoping this part out for the clinician and is requiring the 3D models as input next to the medical images, so the clinician shouldn't spend his time segmenting 3D models from images. This segmentation task will be prepared by Materialise in the primary predicate device Mimics Medical (K183105). This process of preparing some part by Materialise as input for the planning software is exactly as such in the predicate device Mimics Cardiac Planner (K233217).

- *Virtual 3D models used during planning:* The segmentation step of creating the 3D models from images is omitted in the subject device and is expected as input to the subject device. The virtual models used as input to the subject device are in fact created in the primary predicate

- *Software technology*
  While the primary predicate device is a desktop Windows software which is run locally on a computer of the clinician, the subject device is cloud software. This enables the software to be used on multiple platforms without installation. So, while on the back-end both subject and primary predicate device are using the same Materialise technology, the front-end of the application is developed in other programming languages due the environment the software should run in. The front-end programming language is the same as the predicate Mimics Cardiac Planner (K233217) device.

Comparison if technological characteristics with the predicate device (**Mimics Cardiac Planner K233217**)

The Mimics Thoracic Planner employs similar fundamental technologies as Mimics Cardiac Planner. Technological similarities include:

- *Device functionality*
  Both the subject and reference devices share much of the software functionality, including visualization of 3D models, image visualization, measurement tools, and report generation

- *Virtual 3D models used during planning:*
  Both devices, expect created virtual 3D anatomical models as an input. For both virtual models are created in Mimics Medical (K183105).

- *Software technology*
  Both subject and predicate device are based on the same cloud technology and are developed by the same team in Materialise, sharing the same code libraries. Both products are integrated with the same Medical

Device Data System, SurgiCase Online (which is responsible for the case management, user management, etc.).

- *Device design and development process*
  Both predicate and subject software are manufactured by the same company (Materialise NV), the subject device originates from the same code base as the predicate device; and 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.

- *Process in which the software is used*
  Mimics Thoracic Planner is used in a similar process as Mimics Cardiac Planner, where images are uploaded on an online Case Management system, where segmentation on this data is performed as a service by Materialise. The output of this service is then used as input for the Mimics Thoracic Planner (subject device) and Mimics Cardiac Planner (predicate device).

The following technological differences exist between the subject 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 Thoracic).

A device comparison table of the subject, primary predicate, and predicate devices is provided below.

	Subject device **Mimics Thoracic Planner** **K251964**	**Primary Predicate device** **Mimics Medical** **K183105**	**Predicate Device** **Mimics Cardiac Planner** **K233217**
Trade name	Mimics Thoracic Planner	Materialise Mimics Medical	Mimics Cardiac Planner
Common name	Image processing system	Image processing system	Image processing system
Manufacturer	Materialise NV	Materialise NV	Materialise NV
Classification	Product code: LLZ (21 CFR 892.2050) Classification Panel: Radiology Device Class: Class II	Product code: LLZ (21 CFR 892.2050) Classification Panel: Radiology Device Class: Class II	Product Code: LLZ (21 CFR 892.2050) Classification Panel: Radiology Device Class: Class II
Indications for use	The Mimics Thoracic Planner is intended to be used as a pre-procedural planning software to review, analyze and plan pulmonary or thoracic procedures based on DICOM compliant medical images. The Mimics Thoracic Planner allows the clinician to visualize, measure and annotate pre-procedural plan data before and during the procedure, and perform post-op analysis.	Mimics Medical is intended for use as a software interface and image segmentation system for the transfer of medical imaging information to an output file. Mimics Medical is also intended for measuring and treatment planning. The Mimics Medical output can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods.	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

	The Mimics Thoracic Planner allows the clinician to edit pre-procedural plan data before the procedure. The Mimics Thoracic Planner should be used in conjunction with other diagnostic tools and expert clinical judgement.	The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Mimics Medical should be used in conjunction with expert clinical judgement.	pathway of structural heart and vascular devices. Mimics Cardiac Planner should be used in conjunction with other diagnostic tools and expert clinical judgement.
Imaging modality	DICOM compliant imaging information	Medical Imaging information	DICOM compliant imaging information
Design	Mimics Thoracic Planner is a workflow-based software interface for the transfer of medical images to an output planning file. The system provides visualization and measurement tools to enable the user to plan the procedure. Mimics Thoracic Planner reads DICOM compliant medical images from a medical scanner together with the 3D models and landmarks. The software provides different methods to visualize the anatomical structures. Based on the medical images and/or 3D reconstruction measurements are created and visualized. All this will be saved in a digital output file. The output file is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.	Software interface and image segmentation system for the transfer of medical imaging information to an output file. Software for measuring and treatment planning. The physical replicas or anatomical models that can be created with Mimics Medical can have a variety of clinical uses. Besides the clearly non-diagnostic applications (training, education, patient communication), the diagnostic applications of 3D printed models can be divided into two categories: 1. Diagnostic application equivalent with the use of a virtual model 2. Diagnostic application specific to the physical aspect of a 3D printed model (templating) The 3D printed model generated from the Mimics Medical output file plays a role as a supplementary tool only, next to traditional tools for diagnosis and treatment planning, and must be used under supervision of a clinical expert.	Mimics Cardiac Planner is a workflow-based software interface for the transfer of medical images to an output planning file. The system provides visualization and measurement tools to enable the user to plan the procedure. Mimics Cardiac Planner reads DICOM compliant medical images from a medical scanner together with the 3D models and landmarks. The software provides different methods to visualize the anatomical structures. Based on the medical images and/or 3D reconstruction measurements are created and visualized. All this will be saved in a digital output file. The output file is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.
Programming language	C++, Python, C#, JavaScript (TypeScript)	C++	C++, Python, C#, JavaScript (TypeScript)
Operating system	Microsoft Windows, MAC OS, iOS	Microsoft Windows	Microsoft Windows, MAC OS, iOS

Function	Import of images and segmented models Pre-surgical planning through Analyze anatomy: anatomical measurements, 3D and image visualization options Plan resection: resection related views, tools and measurements to select the resection. Plan/keep track of surgical cuts: views and tools to indicate surgical cuts. Intra-op guidance: visualize the plan during the intervention. Functionality is organized into a user guided workflow for better user experience. Integrated with a Medical Device Data System, SurgiCase Online (which is responsible for case management, user management, etc).	Image segmentation Treatment planning Measurements Processing to output file Generation of physical replicas which can be used for diagnostic purposes	Import of images, segmented models and landmarks Pre-surgical planning through Analyze anatomy: anatomical measurements, 3D and image visualization options Plan device: Device selection and positioning and device related measurements Plan delivery: assessing access pathway and access measurements Output : intra-op guidance for fluoro angles Functionality is organized into a user guided workflow for better user experience. Integrated with a Medical Device Data System, SurgiCase Online (which is responsible for case management, user management, etc).
Testing	Software testing Software verification testing Software validation testing	Software verification and validation Segmentation test Orthopedic and CMF Segmentation test Cardiovascular Validation of compatibility with a set of 3D printers with the purpose to generate physical replicas which can be used for diagnostic purposes	Software testing Software verification testing Software validation testing

Conclusion

Following the comparison between the subject and primary predicate device, and between subject and predicate device, it can be concluded that the abovementioned technological differences between the subject and primary 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 predicate device with matching characteristics in the areas where the subject device differs from the predicate, as well as by the 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.

Non-clinical performance testing was performed to verify that Mimics Thoracic Planner provides visualization, measurement, and planning functionality equivalent to the FDA-cleared predicate device, Mimics Medical (K183105). Quantitative functions, including segment and subsegment volumes, and lesion measurements were verified with results meeting predefined acceptance criteria.

Detailed overview on software verification and validation for automated features:

Automated or Semi-automated Feature	Description	Test Method	Conclusion
(sub)segment volume (L)	The volume of each selected segment or subsegment.	Quantitative comparison against predicate device: The volume displayed in Mimics Thoracic Planner must match exactly (0.0% deviation) the volume displayed by the predicate device for the same segment(s)/subsegment(s).	The segment volume displayed equals (0.0% deviation) the volume of the same segment in the predicate device.
(sub)segment volume percentage (%)	The volume percentage of each selected segment or subsegment.	Quantitative comparison against predicate device: The total volume is independently checked against the total calculated in the predicate, to confirm correct summation and display.	The volume percentage and total volume displayed match the predicate device values with 0.0% deviation.
Lesion mean and max diameter (mm)	The mean and maximum diameters of the selected lesion(s). The mean diameter is computed using a sphere-fitting algorithm. The maximum diameter is determined from the maximum internal distance of the 3D object of the lesion.	Quantitative comparison: Compare results against three spheres of known diameters, chosen to represent clinically relevant size ranges based on the NCCN Guidelines V8.2025 - Non-small cell lung cancer. Compare results from five diverse clinical cases against a separately implemented calculation of the same algorithm.	The mean and maximum diameter displayed match the synthetic data with 0.0% deviation. The mean and maximum diameter displayed match the separately implemented algo with 0.1 mm tolerance.

Summary

The characteristics that determine the functionality and performance of the subject device Mimics Thoracic Planner is substantially equivalent to the device cleared under **Mimics Medical (K183105),** 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 Thoracic Planner is substantially equivalent to the predicate device.