May 31, 2024

Materialise NV
Victoria Becheva
Regulatory Affairs Specialist, Medical
Technologielaan 15
Leuven, 3001
Belgium

Re: K223427
Trade/Device Name: Mimics Enlight CMF
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ, DZJ
Dated: May 24, 2024
Received: May 24, 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,

FDA Bobak Shirmohammadi -S

For Michael E. Adjodha, M.ChE., RAC, CQIA
Assistant Director
DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K223427

Device Name
Materialise Mimics Enlight CMF

Indications for Use *(Describe)*
Materialise Mimics Enlight CMF:

Mimics Enlight CMF is intended for use as a software interface and imaging segmentation system for the transfer of medical imaging information to an output file.
Mimics Enlight CMF is also intended to support the diagnostic and treatment planning process of maxillofacial procedures. For this purpose, Mimics Enlight CMF provides visualization, measurement and design tools.
The Mimics Enlight CMF output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The fabricated output can be used for diagnostic purposes in the field of maxillofacial applications.
Mimics Enlight CMF 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.

510(k) Summary - K223427

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
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Postal code	3001
Country	Belgium
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Principal Contact person	Victoria Becheva
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Additional contact person	Polliane Carvalho
Contact title	Regulatory Affairs Specialist
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 November 09, 2022. The Summary was prepared on May 23, 2024.

Submission information

Trade Name	Mimics Enlight CMF
Common Name	Image processing system
Classification Name	System, Image processing, Radiological
Classification product code	LLZ (892.2050), DZJ (872.4120)

Predicate Devices

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

Trade or proprietary or model name	*Materialise Mimics Medical, Mimics Medical, Mimics*
510(k) number	K183105
Decision date	03/27/2019
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

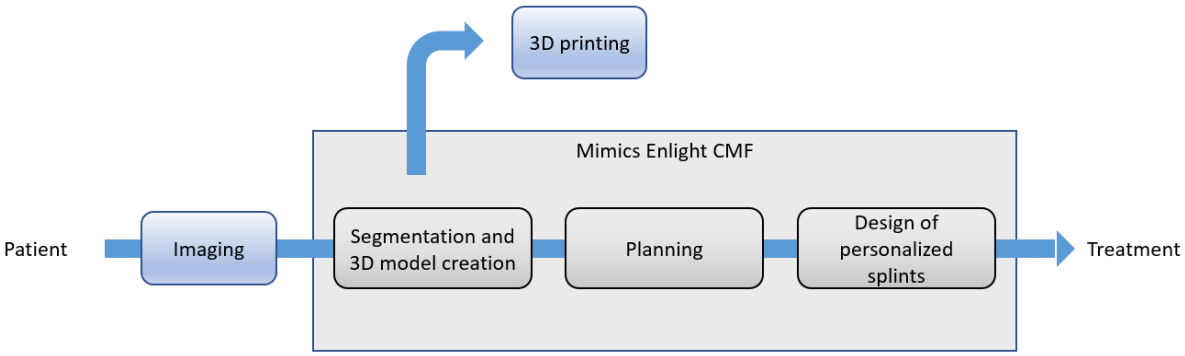
Reference device

Trade or proprietary or model name	SurgiCase, SurgiCase CMF, ProPlan CMF
510(k) number	K111641
Decision date	09/26/2011
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

Trade or proprietary or model name	OsteoPlan System
510(k) number	K212570
Decision date	02/12/2022
Classification product code	DZJ (872.4120)
Manufacturer	OsteoMed

Description and functioning of the device

Mimics Enlight CMF is an image processing software for the diagnosis and treatment planning of maxillofacial procedures. Mimics Enlight CMF allows the user to import, visualize and segment medical images. Mimics Enlight CMF also allows the user to perform measurements, treatment planning and occlusal splint design. Mimics Enlight CMF allows the user to output digital 3D models of the anatomy to be used for fabrication of physical anatomical models. Mimics Enlight CMF is structured as a modular package consisting of separate workflows for the diagnosis and treatment planning of various indications within the maxillofacial field. The workflows in Mimics Enlight CMF are built on the Mimics Enlight platform. The workflows in Mimics Enlight CMF cover following steps and functionality in the diagnostic and treatment planning process of maxillofacial procedures:



Digital 3D model creation

- Importing medical images in DICOM format and other formats
- Viewing images and DICOM data
- Selecting a region of interest using generic segmentation tools
- Verifying and editing a region of interest

- Calculating a digital 3D model and editing the model
- Creating composite models by combining medical image information and dental information using registration tools
- Exporting digital 3D models for additive manufacturing (3D printing) of physical replicas (anatomical models)

Planning

- Indicating nerves and cephalometric landmarks
- Setting the natural head position
- Planning the treatment by cutting the models and repositioning the parts
- Setting the occlusion digitally or by importing an occlusion model
- Measuring on images and digital 3D models
- Simulating the soft tissue of the face after the planned treatment

Design

- Designing personalized digital occlusal splints using generic design and finishing tools

User fabrication using additive manufacturing (3D printing) of physical replicas includes only fabrication of anatomical models and does not include additive manufacturing of occlusal splints.

Indications for Use

Mimics Enlight CMF is intended for use as a software interface and imaging segmentation system for the transfer of medical imaging information to an output file.

Mimics Enlight CMF is also intended to support the diagnostic and treatment planning process of maxillofacial procedures. For this purpose, Mimics Enlight CMF provides visualization, measurement and design tools.

The Mimics Enlight CMF output file can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The fabricated output can be used for diagnostic purposes in the field of maxillofacial applications.

Mimics Enlight CMF should be used in conjunction with other diagnostic tools and expert clinical judgement.

Comparison of Technological Characteristics with the Predicate Device

The subject device employs similar fundamental technologies as the **predicate** device.

Technological similarities include:
Device functionality: The image information and segmentation, the measuring and planning functionality, the processing to output file are the same for the subject device as for the predicate device.

Software technology: The subject device has the same code base as the predicate device and uses the same methods for design and verification and validation as the predicate device.

Following technological differences exist between the subject device software and the predicate device software:

The main difference between the subject device and previously cleared device, K183105 is that the subject device's intended use is limited to -maxillofacial applications, whereas the primary predicate device covers a broader field of orthopedic, maxillofacial and cardiovascular applications.

The subject software technology differences have been demonstrated that they do not affect the safety or effectiveness, or that they do not raise any new issues regarding to the safety and effectiveness compared to the predicate device.

Performance Data

Software verification and validation were performed, and documentation was provided following the "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". This includes verification against defined requirements, and validation against user needs. Both end-user validation and bench testing were performed.

To evaluate the geometrical accuracy of the subject device, virtual models were compared with those of the predicate device. The results revealed no deviations in the virtual models, demonstrating substantial equivalency between the two devices.

For the predicate device, the geometrical accuracy of physical replicas was assessed by comparing virtual models with the optical scans of the physical models. The deviations were found to be within the acceptance criteria, indicating that the virtual models can be printed accurately using one of the compatible 3D printers.

As the virtual models of the predicate and subject devices showed no significant deviations, it can be concluded that compatible 3D printers can produce accurate results for the subject device as well.

Additional testing was done for the soft tissue simulation in the subject device Mimics Enlight CMF. The test demonstrated that the soft tissue simulation in Mimics Enlight CMF is equivalent to the soft tissue simulation in the reference device Proplan CMF (K111641).

In conclusion, all performance testing conducted demonstrated device performance and substantial equivalence to the predicate device.

Summary

A comparison of intended use and technological characteristics combined with performance data demonstrates that Mimics Enlight CMF is substantially equivalent to the predicate device Mimics (K183105), the primary predicate device, and also substantially equivalent to its reference devices Proplan CMF (K111641) and OsteoPlan System (K212570). Minor differences in intended use and technological characteristics exist, but performance data demonstrates that Mimics Enlight CMF is as safe and effective and performs as well as the predicate device.