Materialise NV
% Mieke Janssen
Regulatory Affairs Manager
Technologielaan 15
3001 Leuven
BELGIUM

March 27, 2019

Re: K183105
Trade/Device Name: Mimics Medical
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 11, 2019
Received: March 14, 2019

Dear Mieke Janssen:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Michael D. O'Hara For

Thalia Mills, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183105

Device Name
Mimics Medical

Indications for Use *(Describe)*
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.
The physical replica can be used for diagnostic purposes in the field of orthopaedic, maxillofacial and cardiovascular applications.
Mimics Medical should be used in conjunction with 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.

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510(k) Summary

K183105

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 16 744 571
Fax number	+32 16 39 66 06
Principal Contact person	Mieke Janssen
Contact title	Regulatory Affairs Manager
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Ward Callens
Contact title	Director, Quality and Regulatory affairs
Contact e-mail address	Regulatory.Affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is November 5th, 2018.

Submission information

Trade Name	Mimics Medical, Materialise Mimics Medical
Common Name	Image processing system
Classification Name	System, Image processing, Radiological
Classification product code	LLZ (892.2050)

Predicate Devices

The primary predicate device to which substantial equivalence is claimed:

Trade or proprietary or model name	Mimics
510(k) number	K073468
Decision date	April 2, 2008
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

The reference device:

Trade or proprietary or model name	Mimics inPrint
510(k) number	K173619
Decision date	March 21, 2018
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

Description and functioning of the device

Mimics Medical is image processing software that allows the user to import, visualize and segment medical images, check and correct the segmentations, and create digital 3D models. The models can be used in Mimics Medical for measuring, treatment planning and producing an output file to be used for additive manufacturing (3D printing). Mimics Medical also has functionality for linking to third party software packages. Mimics Medical is structured as a modular package. This includes the following functionality:

- Importing medical images in DICOM format and other formats (such as BMP, TIFF, JPG and raw images)
- Viewing images and DICOM data
- Selecting a region of interest using generic segmentation tools
- Segmenting specific anatomy using dedicated semi-automatic tools or fully automatic algorithms
- Verifying and editing a region of interest
- Calculating a digital 3D model and editing the model
- Measuring on images and 3D models
- Exporting images, measurements and 3D models to third-party packages
- Planning treatments (surgical cuts etc.) on the 3D models
- Interfacing with packages for Finite Element Analysis
- Creating Python scripts to automate workflows

Intended Use

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. 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.

Comparison of Technological Characteristics with the Predicate Device

The subject device Mimics Medical employs similar fundamental technologies as the predicate device. Technological similarities include:

- Device functionality:
    - Image segmentation: The subject and predicate device share the same image segmentation functionalities.
    - Processing to output file: The subject and predicate device both generate an output file.
    - Measuring and planning: The subject and predicate device both have functionalities to perform measurements and pre-surgical planning.
- Device design: The subject device originated from the same code base as the predicate device.

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

- Imaging information: Whereas the predicate device is intended to import imaging information from a medical scanner such as CT or MRI scanner, the subject device is intended to import DICOM compliant types

of imaging information and also supports import of standard imaging formats (such as RAW, TIFF, BMP and jpeg format).

- Device functionality: The subject device shares the technology and functionality of the predicate device. However, for the subject device, functionality was extended to improve the usability for the user.

Comparison of technological characteristics with the ***Reference Device*** (Mimics inPrint, K173619):

The subject device employs similar fundamental technologies as the reference device. Technological similarities include:

- Device functionality:
    - Image segmentation: The subject and reference device share the same image segmentation functionalities.
    - Processing to output file: The subject and reference device both generate an output file.
- Device design: The subject device and reference device originate from the same code base (being the code base of the predicate device).

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

- Imaging information: The reference device is intended to import DICOM imaging information from a medical scanner. The subject device is more generally intended to import imaging information of a medical scanner, allowing both DICOM compatible images and standard imaging formats (such as RAW, TIFF, BMP and jpeg format).
- Device functionality: The subject device shares the technology and functionality of the reference device, but is organized differently (graphical user interface of the software). The functionality of the predicate device is organized in a toolbox fashion, whereas the interface of the reference device specifically guides the user through a few predefined steps for obtaining a 3D printable output file.

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.

The geometric accuracy of virtual models created in the subject device Mimics Medical was assessed via bench testing. This was tested for cardiovascular, orthopedic and maxillofacial models. Accuracy of the virtual models was compared for the subject and predicate device. Deviations were within the acceptance criteria. This shows that for creating virtual models, Mimics Medical is substantially equivalent to the predicate device.

Apart from geometric accuracy of virtual models, also geometric accuracy of physical replicas (produced by 3D printing virtual models) was assessed. This was conducted for cardiovascular, orthopedic and maxillofacial models. The physical replicas were compared to the virtual models. Deviations were within the acceptance criteria, showing that virtual models can accurately be printed when using one of the compatible 3D printers.

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 Medical is substantially equivalent to the predicate device Mimics (K073468). Minor differences in intended use and technological characteristics exist, but performance data demonstrates that Mimics Medical is as safe and effective, and performs as well as the predicate device.