Materialise N.V.
% Mr. Oliver Clemens
Regulatory Affairs Officer
Technologielaan 15
3001 Leuven
BELGIUM

March 21, 2018

Re: K173619
Trade/Device Name: Mimics inPrint
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: February 21, 2018
Received: February 21, 2018

Dear Mr. Clemens:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

For

Robert Ochs, 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)*
K173619

Device Name
Mimics inPrint

Indications for Use *(Describe)*
Mimics inPrint 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. It is also used as pre-operative software for treatment planning. For this purpose, the Mimics inPrint 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 orthopedic, maxillofacial and cardiovascular applications. Mimics inPrint 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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 62 80
Fax number	+32 16 39 66 06
Principal Contact person	Oliver Clemens
Contact title	Regulatory Affairs Officer
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Mieke Janssen
Contact title	Senior Regulatory Officer
Contact e-mail address	Regulatory.Affairs@materialise.be

Submission date

The date of the Traditional 510(k) submission is November 20, 2017

Submission information

Trade Name	*Mimics inPrint*
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 2nd, 2008

Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

The reference device:

Trade or proprietary or model name	D2P
510(k) number	K161841
Decision date	January 9th, 2017
Classification product code	LLZ (892.2050)
Manufacturer	3D Systems, Inc

Description and functioning of the device

Mimics inPrint is an image processing and segmentation software that was built on top of the Mimics application framework, an image processing and segmentation framework for the transfer of imaging information to an output file.

Intended Use

Mimics inPrint 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. It is also used as pre-operative software for treatment planning. For this purpose, the Mimics inPrint 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 orthopedic, maxillofacial and cardiovascular applications. Mimics inPrint should be used in conjunction with other diagnostic tools and expert clinical judgement.

Technological Characteristics

A detailed comparison shows the subject device is substantially equivalent in intended use, design, functionality, operating principles, materials and performance characteristics to the predicate device.

Both the predicate and subject device are intended for use as a software interface and image segmentation system for the transfer of imaging information from a medical scanner to an output file, and can both be used as pre-operative software. Both devices use the same image segmentation functionalities. Both devices generate an output file. Both devices have functionalities to perform pre-surgical planning. 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 both predicates and subject device has been done following the same procedures and workflows.

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

- The subject device's intended use explicitly reflects 3D printing of the output file which can be used for diagnostic purposes in orthopedic, maxillofacial and cardiovascular applications, whereas this was only implicitly included for the primary predicate device
- The subject device only intends to be a software for treatment planning and does not include the simulation of treatment options.
- Whereas the primary predicate device was 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.
- The subject device shares the same technology and functionality as the primary predicate device, however, functionality is organized into a user guided workflow for better user experience.

Performance Data

Non-clinical tests
The **Mimics inPrint** application has been validated for its intended use to determine substantial equivalence to the predicate device. Measurement accuracy and calculate 3D study were performed and confirmed to be within specification. Validation of printing of physical replicas was performed and demonstrated that anatomical models for cardiovascular, orthopedic and maxillofacial cases can be printed accurately when using any of the compatible 3D printers.

Summary

The characteristics that determine the functionality and performance of the subject device, the *Mimics inPrint* are substantially equivalent to the devices cleared under K073468. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicate device.