Materialise NV
℅ Aya Nishikawa
Regulatory Affairs Specialist
Technologielaan 15
Leuven, 3001
BELGIUM

June 15, 2022

Re: K213684
Trade/Device Name: SurgiCase Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: May 6, 2022
Received: May 9, 2022

Dear Aya Nishikawa:

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/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 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 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
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213684

Device Name
SurgiCase Viewer

Indications for Use *(Describe)*
SurgiCase Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options.

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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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	Aya Nishikawa
Contact title	Regulatory Affairs Specialist
Contact e-mail address	Regulatory.Affairs@materialise.be
Additional contact person	Anneleen Van Assche
Contact title	Software Product Manager
Contact e-mail address	Anneleen.VanAssche@materialise.be

Submission date

The date of the Traditional 510(k) submission is November 16th, 2021

Updated:

April 25th, 2022

Submission information

Trade Name	*SurgiCase Viewer* *Materialise Viewer*
Common Name	Image processing system
Classification Name	System, Image processing, Radiological
Classification product code	LLZ (21 CFR 892.2050)

Predicate Devices

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

Trade or proprietary or model name	SurgiCase Viewer
510(k) number	K170419
Decision date	May 11, 2017
Classification product code	LLZ (21 CFR 892.2050)
Manufacturer	Materialise N.V.

The secondary reference device:

Trade or proprietary or model name	*Mimics Medical*
510(k) number	K183105
Decision date	March 27, 2019
Classification product code	LLZ (21 CFR 892.2050)
Manufacturer	Materialise N.V.

Description and functioning of the device

SurgiCase Viewer provides functionality to allow visualization of 3D data and to perform measurements on these 3D data, which should allow a clinician to evaluate and communicate about treatment options.

SurgiCase Viewer is intended for use by people active in the medical sector. When used to review and validate treatment options, SurgiCase Viewer is intended to be used in conjunction with other diagnostic tools and expert clinical judgment.

The **SurgiCase Viewer** can be used by a medical device/service manufacturer/provider or hospital department to visualize 3D data during the manufacturing process of the product/service to the end-user who is ordering the device/service. This allows the end-user to evaluate and provide feedback on proposals or intermediate steps in the manufacturing of the device or service.

The **SurgiCase Viewer** is to be integrated with an online Medical Device Data System which is used to process the medical device or service and which is responsible for case management, user management, authorization, authentication, etc.

The data visualized in the SurgiCase Viewer is controlled by the medical device manufacturer using the SurgiCase Viewer in its process. The Device manufacturer will create the 3D data to be visualized to the end-user and export it to one of the dedicated formats supported by the SurgiCase Viewer. Each of these formats describe the 3D data in STL format with additional meta-data on the 3D models. The SurgiCase Viewer does not alter the 3D data it imports and its functioning is independent of the specific medical indication/situation or product/service it is used for. It's the responsibility of the Medical device company using the SurgiCase Viewer to comply with the applicable medical device regulations.

Intended Use

SurgiCase Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options.

Comparison of Technological Characteristics with the Predicate Device

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

The **subject device SurgiCase Viewer** is equivalent to the **predicate device SurgiCase Viewer (K170419)** in:

- Intended use: Both the subject device as well as the predicate device have the same intended use;
    - They are both intended to be used as a software interface to assist in visualization and communication of treatment options.
- Device functionality:
    - Import plans from dedicated file formats
    - 3D view navigation: updating camera orientation/zooming/panning
    - Visualization options:
        - show/hide, transparency of objects, primitives, measurements
        - ability to visualize predefined views (a view is a preset collection of models/images which are visualized together) optionally including questions to be answered by the end-user
        - clipping of 3D models
    - Measuring
    - Making indications/annotations on the 3D models
- Device architecture/technology: SurgiCase Viewer shares the same architecture/technology and functionality as the primary predicate device, however, functionality was just further extended to improve the usability for the user.

- 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.

The main differences between the subject and the predicate device are:

- Device Functionality: the subject's device functionality was further extended from the predicate device's functionality with:
    - Medical images visualization
        - Including image scrolling, zooming, panning
        - Contrast adjustments
        - Interactive image reslicing
        - 3D contour overlay on images
    - Visualization of 3D models in Virtual Reality

The abovementioned technological differences do not impact the safety and effectiveness of the subject device for the proposed intended use as is demonstrated by the verification and validation plan.

The **subject device SurgiCase Viewer** is substantially equivalent to the secondary **reference device Mimics Medical (K183105)** in:

- Device Functionality
    - Medical images visualization
        - Including image scrolling, zooming, panning
        - Contrast adjustments
        - Interactive image reslicing
        - 3D contour overlay on images
- Device design and development process: Both reference and subject software are manufactured by the same company (Materialise NV), the subject device originates from the same code base as the reference 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.

Differences in technological characteristics of the subject device compared with the reference device Mimics Medical:

- Intended use: While the subject device **SurgiCase Viewer** is intended to be used as a software interface to assist in visualization and communication of treatment options, the reference device Mimics Medical is also intended as an image segmentation system and intended for treatment planning.
- Device Functionality:
    - the reference device functionality is much more extended than the subject device, which only includes a limited subset of functionality from the reference device, due to its different intended use.
- Device architecture/technology: while the reference device Mimics Medical is a Windows based desktop solution, the subject device is a web application which can be used in different browsers and on different operating systems (however the underlying libraries used for image based operations are still the same in both products).

The above mentioned technological differences do not impact the safety and effectiveness of the subject device for the proposed intended use as is demonstrated by the verification and validation plan.

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 with end-users.

The **SurgiCase Viewer** application has been validated for its intended use to determine substantial equivalence to the primary predicate device SurgiCase Viewer.

The medical images functionality was compared to the same functionality present in the secondary reference device Mimics. Both functionality produce the same results in:

- Contrast adjustments
- Interactive image reslicing

- 3D contour overlay on images

Measurement functionality on images was compared with already existing functionality on the 3D models and shown to provide correct results both on images and 3D.

Summary

The characteristics that determine the functionality and performance of the subject device, the *SurgiCase Viewer* are substantially equivalent to the devices cleared under K170419 and K183105. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicates.

From the substantial equivalence analysis we conclude that the intended use and technological characteristics of **SurgiCase Viewer** are substantially equivalent to a combination of the predicate device **predicate device SurgiCase Viewer (K170419)** and the **reference device Mimics Medical (K183105).** Based on the application of risk management and performance testing we conclude that SurgiCase Viewer is as safe and effective as its predicate and reference devices and does not raise any new issues related to safety and effectiveness compared to the predicate and reference devices, and has a comparable performance.