DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 11, 2017

Materialise NV
% Oliver Clemens
Regulatory Officer
Technologielaan 15
Leuven, 3001
BELGIUM

Re: K170419
Trade/Device Name: SurgiCase Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: March 30, 2017
Received: April 3, 2017

Dear Oliver 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170419

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.

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

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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	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 May 11, 2017.

Submission information

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

Predicate Devices

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

Trade or proprietary or model name	*SurgiCase Connect for iPad*
510(k) number	K113599

Decision date	April 27, 2012
Classification product code	LLZ (892.2050)
Manufacturer	Materialise N.V.

The secondary predicate device:

Trade or proprietary or model name	*SurgiCase Connect*
510(k) number	K132290
Decision date	April 10, 2014
Classification product code	PBF (21 CFR 888.3030)
Manufacturer	Materialise N.V.

The reference device:

Trade or proprietary or model name	Materialise TKA Guide System
510(k) number	K150928
Decision date	August 10th, 2015
Classification product code	JWH (21 CFR 888.3560)
Subsequent product codes	MBH, OIY, OOG
Manufacturer	Materialise N.V.

Description and functioning of the device

SurgiCase Viewer provides functionality to visualize 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.

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 primary predicate and secondary predicate devices.

Performance Data

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

Summary

The characteristics that determine the functionality and performance of the subject device, the *SurgiCase Viewer* are substantially equivalent to the devices cleared under K113599 and K132290. The non-clinical testing indicates that the subject device is as safe, as effective, and performs as well as the predicates.