June 3, 2026

CustoMED , Ltd.
% Esther Kott
Director of Regulatory Affairs
LDP Consulting
44 Hey Beiyar St.
Tel Aviv, 6215017
Israel

Re: K260116
Trade/Device Name: CustoMED Viewer
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: [NOTE: Use date of most recent supplement]
Received: April 30, 2026

Dear Esther Kott:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

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

# Indications for Use

| | |
|---|---|
| Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions. | K260116 |

Please provide the device trade name(s).

CustoMED Viewer

Please provide your Indications for Use below.

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

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**K260116 510(k) SUMMARY**

**CustoMED Viewer**

| | |
|---|---|
| **Company's Name and Address** | CustoMED Ltd.<br>Derech Shiba 64<br>Ramat Gan<br>5266200<br>Israel |
| **Contact Person** | Esther Kott<br>Director of Regulatory Affairs<br>LDP Consulting<br>esther@ldp-consulting.com<br>+972-58-488-7454 |
| **Date Prepared** | June 1, 2026 |
| **Device Tradename** | CustoMED Viewer |
| **Classification Name** | System, Image processing, Radiological |
| **Regulation Name** | Medical Image Management and Processing System |
| **Product Code** | LLZ |
| **Classification** | 21 CFR 892.2050 |
| **Predicate Device** | SurgiCase Viewer (K170419) |
| **Device Description** | CustoMED Viewer was developed to allow medical professionals (surgeons) and service providers (designers or engineers assisting in planning the surgery) to communicate more effectively during procedures planning. It enables its end users, the medical professionals (e.g., ordering surgeons), to review and provide feedback on design proposals or intermediate outputs, ensuring alignment with clinical expectations.<br><br>The surgeon uploads a DICOM file to the CustoMED Viewer which is shared with the service provider. The service provider uses FDA-cleared third-party software for surgical planning and creates 3D data to upload to the viewer in stl format. The CustoMED Viewer is used only for visualization and does not include any algorithmic or AI/ML functionality.<br><br>The CustoMED 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 is the responsibility of the service provider using the CustoMED Viewer to comply with the applicable medical device regulations. |
| **Indications for Use** | CustoMED Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options. |
| **Intended Use** | CustoMED Viewer is intended to be used as a software interface to assist in the visualization and communication of treatment options. The device displays three-dimensional anatomical models derived from CT imaging data for visualization and review by qualified healthcare professionals, and perform basic measurements on that data. |
| **Technological Characteristics** | A comprehensive assessment demonstrates the subject device is substantially equivalent in intended use and indications for use, technological characteristics, and principles of operation to the |

predicate device, as shown in the Technological Characteristics Table below.

**Technological Characteristics Table:**

| Comparison Feature | | Subject Device CustoMED Viewer (K260116) | Predicate Device SurgiCase Viewer (K170419) | Comparison |
|---|---|---|---|---|
| Device Class | | Class II | Class II | Identical |
| Classification Panel | | Radiology | Radiology | Identical |
| Product Code | | LLZ | LLZ | Identical |
| Regulation Description | | Picture archiving and communications system | Picture archiving and communications system | Identical |
| Regulation Number | | 892.2050 | 892.2050 | Identical |
| Indications for Use | | CustoMED Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options. | SurgiCase Viewer is intended to be used as a software interface to assist in visualization and communication of treatment options. | Identical |
| Clinical Characteristics | | | | |
| Indications of Use | | General indication for use | General indication for use | Identical |
| Type of scans | | CT | CT / MRI | Similar |
| Application/Anatomy | | General indication for use | General indication for use | Identical |
| Primary Imaging Modalities | | Upload by user: CT / STL | Upload by the service provider: CT / STL (by integration) | Similar |
| DICOM/CT Viewer | | Yes | Yes | Identical |
| 3D Reconstruction/ Segmentation | | Uploaded by the service provider: STL | Uploaded by the service provider: STL (by integration) | Identical |
| Intended User(s) | | ● Medical professionals<br>● Service providers | ● Medical professionals<br>● Service providers | Identical |
| Technological features | | | | |
| Segmentation Review and Annotation | | ● View (CT Viewer)<br>● 3D reconstruction visualization<br>● Segmentation slice overlay<br>● Annotation (Drag and Drop)<br>● Approve/Decline by clicking on a button | ● View (CT Viewer)<br>● 3D reconstruction visualization<br>● Segmentation slice overlay<br>● Annotation (Comment)<br>● Approve/Decline by comment | Similar – very minor difference in approve/decline process. This difference does not raise different questions of safety and effectiveness. |
| Landmarks Review and Annotation | Landmarks Annotation | ● Landmark plane<br>● Landmark line (2+ points)<br>● Landmark point | ● Commenting (text)<br>● Draw line (text) | Different – does not raise new questions of safety or effectiveness |
| | Measurements Annotation | ● Distances value (mm) + Visualization (3d)<br>● Angles value (°) + Visualization (3d) | ● Distances value (mm) + Visualization (3d)<br>● Angles value (°) + Visualization (3d)<br>● Draw and measure area (mm2) | Similar |
| Planning Review | Implants Selection | Template selection (list) | Template selection by comments addressed to the service provider (either by text in the Viewer, or using external tools) | Different – does not raise new questions of safety or effectiveness |

| Comparison Feature | | Subject Device CustoMED Viewer (K260116) | Predicate Device SurgiCase Viewer (K170419) | Comparison |
|---|---|---|---|---|
| | Surgical Plan Annotation | ● Drag and drop or rotating by a gizmo (manipulator) elements (translation)<br>○ 3D Landmarks<br>○ 3D Implants<br>○ 3D Cutting plan<br>○ 3D Drilling cylinder | ● Commenting (text)<br>● Draw line (text)<br>● Draw area (text) | Different – does not raise new questions of safety or effectiveness |
| | Device/PSI Design | ● View (CT Viewer)<br>● 3D anatomy visualization<br>● 3D PSI visualization<br>● Landmark Point Annotation<br>● Annotation (Drag and Drop)<br>● Selection (list/dropdown) | ● View (CT Viewer)<br>● 3D anatomy visualization<br>● 3D PSI visualization<br>● Draw line (text)<br>● Annotation (Comment) | Different – does not raise new questions of safety or effectiveness |

**Performance Data**

No Clinical tests

CustoMED Viewer is a software medical device for which performance testing demonstrates substantial equivalence to the predicate device and confirms that it is as safe and effective as the predicate device.

Performance of the CustoMED Viewer is supported by software verification and validation testing, including verification of linear (distance) and angular measurements accuracy (± 1 mm or ± 1°, respectively) of the measurements performed by the subject device.

**Substantial Equivalence**

The CustoMED Viewer is as safe and effective as its predicate device, the Materialise N.V. SurgiCase Viewer (K170419). Both devices have similar intended use and indications for use, technological characteristics, and principles of operation, as shown in the Technological Characteristics Table above.

Both CustoMED Viewer and SurgiCase Viewer share the same core technological characteristics: they are web-based Software that visualize pre-generated CT-based 3D anatomical data (.STL), support DICOM viewing with 3D overlays, allow user-driven measurements and annotations, and do not modify source data or generate treatment plans autonomously. Some minor technological differences exist between CustoMED Viewer and the predicate device, for example the predicate relies mainly on text-based annotations and comments attached to specific locations whereas the CustoMED Viewer allows clinicians to communicate changes by drag-and-drop annotation, SurgiCase supports MRI data and area measurements (mm²), which CustoMED does not etc. These minor technological differences between the CustoMED Viewer and its predicate device raise no new issues of safety or effectiveness.

**Conclusion**

Evaluation of intended use and indications for use, technological characteristics, and principles of operation, and performance testing, demonstrates that CustoMED Viewer is as safe and effective as its substantially equivalent predicate device.