MySegmenter Technologies Inc.
Ketan Jajal
Chief Executive Officer
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DOVER, DELAWARE 19901

April 16, 2025

Re: K242647
Trade/Device Name: MySegmenter (v2.0.0)
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical Image Management And Processing System
Regulatory Class: Class II
Product Code: LLZ
Dated: March 14, 2025
Received: March 14, 2025

Dear Ketan Jajal:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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
Assistant Director
Imaging Software Team
DHT8B: Division of Radiologic 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242647

Device Name
MySegmenter (v2.0.0)

Indications for Use *(Describe)*
MySegmenter (v2.0.0) is a medical images segmentation tool that converts CT and MRI scans into 3D anatomical models. The models are intended for surgical planning or educational purposes but are not to be used in the operating room.

The software must be used under the supervision of qualified medical professionals. The 3D models and replicas are to be utilized solely for pre-operational planning in orthopedic and craniomaxillofacial cases, and for educational purposes; they must not be used in the operating room. The MR images have not been tested for craniomaxillofacial applications

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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1. Submission Sponsor

MySegmenter Technologies Inc.

2. Submission Correspondent:

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4. Date Summary Prepared: 16 August, 2024

5. Device name & classification:

Trade/Proprietary Name: MySegmenter (v2.0.0)
Common/Usual Name: MySegmenter
Device classification Regulation: 21CFR Part 892.2050
Product Code: LLZ
Device Class: Class 2
Classification Panel: Radiology
Application number: K242647

Predicate utilized: Materialise Mimics Medical 21.0

Introduction

The MySegmenter (v2.0.0) is a post-processing tool for medical image segmentation. It is designed for use by surgeons, medical imaging technologists, and medical device designers. The selection of the appropriate anatomical region for each patient case is determined by the user. MySegmenter provides a 3D visualization environment to view a patient's anatomy, creating a 3D augmented model derived from CT and MRI scans in DICOM format. This software enables detailed visualization and planning based on patient-specific imaging data.

Device Description

MySegmenter (v2.0.0) is a software platform for visualizing medical images in 3D mesh format. processes images by analyzing the luminance of individual pixels to segment and highlight the regions of interest (specific anatomical areas). MySegmenter supports editing, modification and manipulation of segmented areas using various segmentation tools. The software features include:

- Importing medical images in DICOM and other formats.
- Viewing and navigating through DICOM images.
- Segmenting selected regions using generic tools (segments, island effects, Boolean operations, etc.)
- Editing segments with multiple slice edits, fast marching, watershed effects, etc.
- Generating editable 3D STL files for different applications.
- Converting the segment to mesh models.
- Exporting the segmented models in STL format suitable for further manipulation and manufacturing.

Indications for use

MySegmenter (v2.0.0) is a medical images segmentation tool that converts CT and MRI scans into 3D anatomical models. The models are intended for surgical planning or educational purposes but are not to be used in the operating room.
The software must be used under the supervision of qualified medical professionals. The 3D models and replicas are to be utilized solely for pre-operational planning in orthopedic and craniomaxillofacial cases, and for educational purposes; they must not be used in the operating room. The MR images have not been tested for craniomaxillofacial applications.

Comparison of technological parameters

The subject and its predicate devices are platforms to transfer the medical images into workable 3D mesh models that can be used for certain medical purpose such as visualization, planning, customized solutions etc. The comparison mentioned in the table below.

	Subject	**Primary Predicate**
Name	MySegmenter (v2.0.0)	Mimics Medical 21.0
Regulation Number	21 CFR Part 892.2050	21 CFR Part 892.2050
Product Code	LLZ	LLZ

Indication for use	MySegmenter (v2.0.0) is a medical images segmentation tool that converts CT and MRI scans into 3D anatomical models. The models are intended for surgical planning or educational purposes but are not to be used in the operating room. The software must be used under the supervision of qualified medical professionals. The 3D models and replicas are to be utilized solely for pre-operational planning in orthopedic and craniomaxillofacial cases, and for educational purposes; they must not be used in the operating room. The MR images have not been tested for craniomaxillofacial applications.	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. Mimics Medical should be used in conjunction with expert clinical judgement.
Patient population	Adult population (+18)	Unspecified
Clinical use	Pre-operative planning, visualization and diagnostic aid for orthopedic, and craniomaxillofacial cases.	Visualising medical imaging information to an output file, measuring and treatment planning, diagnostic aid for orthopaedic, maxillofacial, and cardiovascular applications
Component	Standalone software	Standalone software
Connectivity	License based	License based
Images formats supported	DICOM images	DICOM, BMP, JPEG images

Key Featured functionalities	The following features are included in MySegmenter: • Manual and Semi-automatic tools for segmentation. • Measurement tools for annotations. • 3D rendering visualization functionality. • Anonymization functionality. • Video recording module.	The following features are included in Materialise Mimics: • Manual, and Semi-automatic tools for segmentation. • Measurement tools for annotation • 3D rendering visualization functionality. • Anonymization functionality. • Video recording module. • Aligning tools • Among other features
Operating system	64-bits Microsoft Windows 10 or superior (Recommended 64-bits Microsoft Windows 11)	64-bit Microsoft Windows 10 or superior
Graphical user interface	Yes	Yes
Network required	Yes	Yes

Performance data:

The following performance data supports the conclusion of equivalence between MySegmenter (v2.0.0) and the predicate device:

Software verification and validation testing:

Verification and validation were conducted according to the "Guidance for the Content of Premarket submission for software contained in Medical Devices". The analysis concluded that the software has a moderate level of concern.

The following tests were performed: Unit testing, Functional testing, Integration testing, System testing, User acceptance testing, Software performance testing, and API testing. These tests were conducted by developers and testers to ensure the proper compliance with all software requirements.

Accuracy studies:

The outputs of the MySegmenter (v2.0.0) were evaluated through various accuracy studies to ensure that the final virtual and printed models accurately represent the original structures and can be utilized for their intended purposes. Detailed findings are provided below:

1. **CT and MRI Accuracy Studies:**
   This study utilized 30 dataset samples (15 CT and 15 MRI) from Indian origin, evenly distributed between adult male and female subjects, in order to ensure diversity and

generalizability in the data. The datasets include craniomaxillofacial and orthopedic models from CT scans, and orthopedic models from MRI.

The samples were acquired from 11 different scanners, using collection protocols that ensured a slice thickness less than or equal to 1 mm for CT images, 2 mm for MRI images, and a minimum resolution for both of at least 512×512 for all orthopedic and craniomaxillofacial cases, in order to guarantee an adequate quality in all the generated models.

For the truthing process, reference models were created using the predicate device by experts in the field of medical imaging. Inter-expert agreement was evaluated using Intraclass Correlation Coefficient (ICC) scores to ensure absolute agreement.

The virtual outputs generated by MySegmenter were compared with those from the predicate device for both orthopedic and maxillofacial models. The performance was assessed using DICE and Jaccard similarity coefficients for volume, with results ranging from 90% to 98% depending on the use of manual editing. Also, the surface accuracy was evaluated using Hausdorff distance, with all models showing deviations below 0.6 mm which falls within the acceptance criteria of 1 mm established. These results indicate that MySegmenter (v2.0.0) provides digital models with a precision substantially equivalent to the predicate device.

2. **3D Printing accuracy:**

This study utilized 20 dataset samples (15 CT and 5 MRI) from Indian origin, evenly distributed between adult male and female subjects, in order to ensure diversity and generalizability in the data. The datasets included craniomaxillofacial and orthopedic applications from CT scans, and orthopedic models from MRI. Samples were obtained from at least 10 different scanners, using collection protocols that ensured a slice thickness less than or equal to 1 mm for CT images, 2 mm for MRI images, and a minimum resolution for both of at least 512×512 for all orthopedic and craniomaxillofacial cases, in order to guarantee an adequate quality in all the generated models.

The applications selected for printing test represented some of the most common and critical clinical scenarios, including fracture malunions, hip dysplasia, and congenital scoliosis in orthopedic cases; and cranial and mandible complex fractures, temporomandibular joint (TMJ) disorders, and mandibular neoplasms in craniomaxillofacial cases.

In this study, clinical models generated by MySegmenter (v2.0.0) were 3D printed, scanned, and compared against digital models produced by the predicate device to validate their precision. Geometric accuracy was assessed using surface-to-surface comparisons via Hausdorff distance. The differences between models were consistently below 1 mm, even in the most critical scenarios. These results confirm that the printed models were within acceptable accuracy limits for the intended applications established for this device.

Summary:

In conclusion, the testing data indicates that MySegmenter (v2.0.0) is substantially equivalent in performance and intended use to the predicate device, Materialise Mimics 21.0 (K183105).

While there are minor differences in algorithms, features and performance, the testing results confirm that MySegmenter (v2.0.0) is as safe, and effective as the predicate device.