



Medviso AB  
% Einar Heiberg, Ph.D.  
Founder, Vice President, CTO  
Griffelvägen 3  
Lund, SE-22467  
SWEDEN

May 6, 2022

Re: K211966  
Trade/Device Name: Segment 3DPrint  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Medical image management and processing system  
Regulatory Class: Class II  
Product Code: LLZ  
Dated: March 30, 2022  
Received: April 8, 2022

Dear Einar Heiberg:

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 and Part 809); 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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

For

Thalia T. Mills, Ph.D.  
Director  
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

510(k) Number (if known)

K211966

Device Name

Segment 3DPrint

Indications for Use (Describe)

Segment 3DPrint is a software for review and segmentation of images from a medical scanner as well as of medical 3D models. Segment 3DPrint is intended to generate 3D models for diagnostic purposes in both paediatric and adult populations in the field of orthopaedic, maxillofacial, and cardiovascular applications. The models can be used for visualisation, measuring, and treatment planning. Output from Segment 3DPrint can be used to fabricate physical replicas, by use of additive manufacturing methods. Segment 3DPrint is intended to be used by medically trained professionals in conjunction with 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.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
PRASStaff@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."*

## 5 510 (k) Summary

### 5.1 Submitter

Medviso AB  
Griffelvägen 3  
SE-224 67 Lund, Sweden  
+46(0)761-836442

**Date Prepared:** May 4, 2022

**Contact Person:** Einar Heiberg, PhD, CTO, +46(0)761-836442,

[enar@medviso.com](mailto:enar@medviso.com)

### 5.2 Device

**Device Trade Name:** Segment 3DPrint

**Device Common Name:** Image processing system

**Classification Name:** Class II – System, Image Processing

**Regulation Number:** 892.2050(Medical image management and processing system)

**Product Code:** LLZ

### 5.3 Predicate Device

**Mimics Medical** (K183105)  
Materialise N.V.  
Technologielaan 15  
3001 Leuven  
Belgium

### 5.4 Device Description

#### Device Description

**Segment 3DPrint** is a software for review and segmentation of images from a medical scanner as well as of medical 3D models. **Segment 3DPrint** is intended to generate 3D models for diagnostic purposes. The models can be used for visualisation, measuring, and treatment planning. Output from **Segment 3DPrint** can be used to fabricate physical replicas, by use of additive manufacturing methods.

Medical images and 3D models may be imported from various sources, including images stored on portable media, network storage devices, and other vendor systems.

**Segment 3DPrint** meets the identification criteria LLZ 892.2050 — Picture archiving and communications system. **Segment 3DPrint** is a software with the capability to import and display medical images and to perform digital processing of a rendered 3D object. **Segment 3DPrint** is a support tool with the means of generating 3D models and should be used by medically trained professionals in conjunction with expert clinical judgement.

The user will interact with **Segment 3DPrint** through a graphical user interface on a standard PC platform, using Windows operating system.

## 5.5 Intended Use

**Segment 3DPrint** is a software for review and segmentation of images from a medical scanner as well as of medical 3D models. **Segment 3DPrint** is intended to generate 3D models for diagnostic purposes in both paediatric and adult populations in the field of orthopaedic, maxillofacial, and cardiovascular applications. The models can be used for visualisation, measuring, and treatment planning. Output from **Segment 3DPrint** can be used to fabricate physical replicas, by use of additive manufacturing methods. **Segment 3DPrint is intended to be used by medically trained professionals in conjunction with expert clinical judgement.**

### Comparison with Predicate Device

Both **Segment 3DPrint** and the predicate device Mimics Medical are support tools which provide the healthcare professional(s) with relevant clinical data to support clinical decisions by analyzing the generated 3D models.

Both **Segment 3DPrint** and Mimics Medical can be used for the fabrication of physical replicas of the output file using additive manufacturing methods.

The intended use for **Segment 3DPrint** is substantially equivalent to the intended use of the predicate device Mimics Medical.

## 5.6 Technological Characteristics

**Segment 3DPrint** and the predicate device are both software packages that can be used for visualization and segmentation of medical images. Both **Segment 3DPrint** and the predicate device provide a user interface with items for selecting images and adjusting image viewing and can be operated from a personal computer. The subject device and predicate device render segmentations of the region of interest either semi-automatically, manually, or in combination, providing digital 3D models. The technological difference between the subject device and the predicate device is that different algorithms are used for the semi-automatic segmentation approaches. There might be slight differences in features and menu, but these differences between the

predicate device and the proposed device are not significant since they do not raise any new or potential safety risks to the user or patient and questions of safety or effectiveness. Based on the results of software validation and verification tests, we conclude that **Segment 3DPrint** is substantially equivalent to the predicate device.

System	Segment 3DPrint	Mimics Medical
Version	3.2	23.0.2
Manufacturer	Medviso AB	Materialise NV
510(k) number	K211966	K183105
Classification	892.2050 LLZ, Class II	892.2050 LLZ, Class II
Intended use	same	same
Patient population	All with images from medical scanner.	Unspecified
Graphical user interface	Yes	Yes
Platform	PC	PC
Operating system	MS Windows 10	MS Windows 10
Image display monitor	Unspecified	Resolution of 1280x1024 or higher
Report display monitor	No	No
Patient demographics	Yes	Yes
Networking	TCP/IP	TCP/IP
DICOM compliant image compression	Lossless	Lossless
Image communication	Yes	Yes
Image processing annotations	Yes	Yes
Linear measurement tools	Yes	Yes
Automatic and manual segmentation of object	Yes	Yes
Automatic filling and smoothing tools	Yes	Yes
Local and remote image storage	Yes	Yes
Type of software – custom integrated	Yes	Yes
Viewing	Yes	Yes
Safety - For use only by a licensed professional	Yes	Yes

## 5.7 Performance Data

The following performance data were provided in support of the substantial equivalence determination.

The accuracy of the final 3D model generated by **Segment 3DPrint** is < 1 mm.

### **Software Verification and Validation Testing**

Software verification and validation testing were conducted and documented according to FDA's Guidance "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices". It was concluded that **Segment 3DPrint** was considered to be of "moderate" level of concern. Extensive testing of the software package is performed by an automated test suite prior to commercial release. As a complement to this, manual testing is performed by Application specialists and the software is evaluated at one beta test site.

### **Bench and Clinical Studies**

The features for **Segment 3DPrint** have been clinically evaluated using bench and clinical studies. The studies are validation or application studies using established methods as reference standards, and were performed in Europe.

The device validation study validates digital models and 3D models from additive manufacturing (low force stereolithography), representative of the three different application areas. In total 12 models, representing the most complex structures and worst-case scenarios, were printed. The patient characteristics for the validation of the print accuracy included four females and eight males. Mean age was  $26 \pm 29$  years, range 15 days - 79 years. Five cases were maxillofacial, three cases were orthopaedic, and four cases were cardiovascular. This yielded replicas with an accuracy of <1 mm, well suited for clinical use in all intended patient population groups.

AI bone segmentation algorithm was trained on 20 data sets, and 21 data sets were used for its validation. There was no overlap of data between the two sets, and care was taken to include a great variety of data (such as scanner model, image quality, and anatomy). The maximum 95th percentile surface distance between the ground truth segmentation and the resulting image was <1 mm.

The patient characteristics for the validation of the AI bone segmentation includes ten females, four males and seven of unknown sex. Mean age was  $33 \pm 26$  years, range 15 days - 76 years. Table 1 below presents the agreement between reference segmentation by expert readers and the segmentation by the automatic segmentation algorithm.



Table 1 - Dice is dice coefficient, Jacc is Jaccard score,  $||Dist||$  is mean $\pm$ SD absolute distance, Dist is signed distance difference, and 95<sup>th</sup> is the 95<sup>th</sup> percentile of the absolute distance.

Set	Dice	Jacc	$  Dist  $ [mm]	Dist [mm]	95 <sup>th</sup> percentile [mm]
Mean	0.96	0.92	0.23	0.03	-
SD	0.03	0.05	0.18	0.26	-
Max	-	-	-	-	0.93

The results of the studies show that the values from the evaluated features in **Segment 3DPrint** were in good agreement with values from the reference method.

No adverse events, or complications, associated with the subject device were observed in the studies. Based on the clinical performance as documented in the performance studies, **Segment 3DPrint** was found to have a safety and effectiveness profile that is similar to the predicate device.

## 5.8 Conclusion

We conclude that the subject device **Segment 3DPrint** is as safe and effective as the predicate device. All identified hazards for **Segment 3DPrint** have been mitigated to acceptable levels, and the overall residual risk evaluation concluded that the residual risk of **Segment 3DPrint** is acceptable. The risks associated with the use of **Segment 3DPrint** are acceptable when weighed against the benefits for the patient. **Segment 3DPrint** performs in accordance with its intended use as well as the predicate device. Identical to the predicate device, **Segment 3DPrint** does not in any way alter the imaging data in the analytical process. **Segment 3DPrint** provides assistance to a medically trained professional and all of the information is subject to his/her oversight, control, and clinical judgement. Medviso AB considers the features of **Segment 3DPrint** to be substantially equivalent to the subset of features in the predicate device Mimics Medical.