April 22, 2022

MirrorMe3D, LLC
℅ Jordan Mills
Chief Executive Officer
222 W 37th Street, Suite 1501
NEW YORK NY 10018

Re: K212981
Trade/Device Name: MirrorMe3D Modeling System
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: March 21, 2022
Received: March 22, 2022

Dear Jordan Mills:

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,

For

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and 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)*
K212981

Device Name
MirrorMe3D Modeling System

Indications for Use *(Describe)*
The MirrorMe3D Modeling System is intended for use as an image processing system for the transfer of 3D medical images. The MirrorMe3D Modeling System is also intended as a visualization system for measuring and treatment planning for aesthetic facial soft tissue. The input data is processed by the System using off-the-shelf modeling software and the result is an output data file that may then be provided as a digital model or used as input for the additive manufacturing of a physical anatomic model, which is not for diagnostic use. The MirrorMe3D Modeling System should only be used in conjunction with expert clinical judgment and is not intended for diagnostic use. MirrorMe3D trained personnel will use off-the-shelf software to assist users in creating the 3D virtual (or digital) model that depicts the surgeon's intended outcome. The anatomic models are not for diagnostic use.

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

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hello@mirrorme3d.com

222 W 37th Street
Suite 1501
New York, NY 10018

A. SUBMITTER

Submitter Name	MirrorMe3D, LLC
Submitter Address	222 W 37th St., Suite 1501, New York, NY 10018
Contact Person:	Jordan Mills (jordan@mirrorme3d.com)
Phone/Fax Numbers:	212-376-4546 / 914-350-4697
Date of Submission:	April 19, 2022

B. DEVICE IDENTIFICATION & MANUFACTURER

Name of Device	MirrorMe3D Modeling System
Common Name	MirrorMe Modeling
Classification Name	21 CFR 892.2050 Medical image management and processing system
Classification Code	LLZ
Regulatory Class	II

C. PRIMARY, SECONDARY PREDICATE AND REFERENCE DEVICES

Primary Predicate Device: K183105, Materialise Mimics Medical
Secondary Predicate: K161634, ISP CaseDesigner
Reference Device: K192282, MedCAD AccuPlan® System
The predicate, the secondary predicate and the reference devices have not been subject to a design-related recall.

D. DEVICE DESCRIPTION

The MirrorMe3D Modeling System is image processing software that enables the input and visualization of 3D medical imaging with output files that can be virtual or physical 3D anatomic models. The Modeling System software is used for visualization of preoperative treatment planning options, with measurement functionality, for surgery of the aesthetic facial soft tissue.

MirrorMe3D trained personnel will process the input data using off-the-shelf software and assist doctors in visualizing treatment plan options. The digital models created under the direction of doctors can then be additively manufactured or 3D printed to provide the surgeon with physical replicas of the digital models. The anatomic models

are not for diagnostic use, do not have any contact with the patient and are not intended for use in a surgical environment. Patient-specific documentary reports will contain screenshots of the virtual models and depict dimensional differences.

E. INDICATIONS FOR USE

The MirrorMe3D Modeling System is intended for use as an image processing system for the transfer of 3D medical images. The MirrorMe3D Modeling System is also intended as a visualization system for measuring and treatment planning for aesthetic facial soft tissue. The input data is processed by the System using off-the-shelf modeling software and the result is an output data file that may then be provided as a digital model or used as input for the additive manufacturing of a physical anatomic model, which is not for diagnostic use. The MirrorMe3D Modeling System should only be used in conjunction with expert clinical judgment and is not intended for diagnostic use. MirrorMe3D trained personnel will use off-the-shelf software to assist users in creating the 3D virtual (or digital) model that depicts the surgeon's intended outcome. The anatomic models are not for diagnostic use.

F. PREDICATE DEVICES

The intended use of the MirrorMe3D Modeling System and its predicate devices, the Materialise Mimics Medical (K183105) and ISP CaseDesigner (K161634) are substantially equivalent. The MedCAD AccuPlan® System (K192282) has been included as a reference device to address the minor differences in technological characteristics between the MirrorMe3D System and the primary and secondary predicates. The subject device, predicates and reference systems are intended for use in the transfer and processing of medical data and the visualization of treatment plan options, with 3D models as the output.

	MirrorMe3D Modeling System	Primary Predicate Device: Materialise Mimics Medical, K183105	Secondary Predicate Device: ISP CaseDesigner K161634	Reference Device: MedCAD AccuPlan®, K192282
REGULATORY CLASSIFICATION	II 892.2050 LLZ	II 892.2050 LLZ	II 892.2050 LLZ	II 892.2050 and 872.4120 DZJ, LLZ
INDICATIONS FOR USE	The MirrorMe3D Modeling System is intended for use as an image processing system for the transfer of 3D medical images. The MirrorMe3D Modeling System is also intended as a visualization system for measuring and treatment planning for aesthetic facial soft tissue. The input data is processed by the System using off-the-shelf modeling software and the result is an output data file that may then be provided as a digital model or used as input for the additive manufacturing of a physical anatomic model, which is not for diagnostic use. The MirrorMe3D Modeling System should only be used in conjunction with expert clinical judgment and is not	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. The Mimics Medical output can be used for the fabrication of physical replicas of the output file using traditional or additive manufacturing methods. The physical replica can be used for diagnostic purposes in the field of orthopedic, maxillofacial and cardiovascular applications. Mimics Medical should be used in conjunction with expert clinical judgement.	IPS CaseDesigner is indicated for use as a software and image segmentation system for the transfer of imaging information from a scanner such as a CT scanner. It is also indicated to support the diagnostic and treatment planning process of craniomaxillofacial procedures. IPS CaseDesigner facilitates the service offering of individualized surgical aids.	The MedCAD® AccuPlan® System is intended for use as a software system and image segmentation system for the transfer of imaging information from a medical scanner such as a CT based system. The input data file is processed by the MedCAD® AccuPlan® System and the result is an output data file that may then be provided as digital models or used as input to a rapid prototyping portion of the system that produces physical outputs including anatomical models, surgical guides and dental splints for use in maxillofacial surgery. The surgical guides and dental splints are intended to be used for the maxillofacial bone in maxillofacial surgery. The MedCAD® AccuPlan® System is also intended as a pre-operative software tool

	intended for diagnostic use. MirrorMe3D trained personnel will use off-the-shelf software to assist users in creating the 3D virtual (or digital) model that depicts the surgeon's intended outcome. The anatomic models are not for diagnostic use.			for evaluating surgical treatment options.
DEVICE TYPE, USAGE	Patient specific, Single Use	Patient specific, Single Use	Patient specific, Single Use	Patient specific, Single Use
SURGICAL SITES	External maxillofacial soft tissue	Orthopedic, maxillofacial, and cardiovascular applications	Cranio-maxillofacial including soft tissue	Maxillofacial surgery
INPUT FILE FORMATS	.OBJ, .MTL and other formats (such as TIFF, JPG, .PNG and raw images	DICOM and other formats (such as BMP, TIFF, JPG, and raw images)	DICOM from CT/CBCT, STL	CT based
DEVICE FUNCTION-ALITY	Transferring and viewing medical imaging; Processing to output file; Measuring and treatment planning on 3D models	Transferring and viewing medical imaging; Image segmentation; Processing to output file; Measuring and treatment planning on 3D models	Transferring and viewing medical imaging; Image segmentation; Processing to output file; Measuring and treatment planning on 3D models	Transferring and viewing medical imaging; Image segmentation; Processing to output file; Measuring and Treatment planning on 3D models

TREATMENT PLANNING / APPROVAL	Surgeons virtually visualize and plan treatment options. Virtual models are created by trained MirrorMe3D employees and must be approved by the surgeon before being manufactured.	Users create the digital 3D models and should be used in conjunction with expert clinical judgment	Surgeons (or clinicians) virtually plan the surgery	Utilized by trained MedCAD employees with the approval of the surgeon before being manufactured.
OUTPUT	Additively manufactured anatomic Models for visual use only; documentary reports	Additively or traditionally manufactured physical replicas for diagnostic use	Patient specific 3D Surgical models and surgical splints	Rapid prototyping of anatomical models, surgical guides and dental splints; case reports
SOFTWARE FOR PLANNING	Commercial off-the shelf software.	Image processing software	Image processing software	Commercial off-the shelf software
Diagnostic Use	No	Yes	Yes	No

Summary

1. The subject device, predicate, secondary predicate, and reference systems are intended for use in the transfer and processing of medical data with 3D models as the output.
2. The subject device, predicate, secondary predicate, and reference device are 3D visualization systems for measuring and treatment planning.
3. The subject device, predicate, secondary predicate, and reference device start with medical imaging provided by a doctor then use software for manipulation in order to create virtual 3D models that reflect the doctor's intended treatment plan.
4. The subject device, primary predicate, and reference systems produce an output file that is used for the additive manufacture of anatomic models, with the difference that the physical models by the subject device are not for diagnostic use.
5. The outputs of all are prescriptive, patient-specific, and single use devices intended for use solely by Doctors, not Patients.
6. The subject device and the reference systems include documentary or case reports as output.
7. The MirrorMe3D System is more limited in its application to the facial soft tissue, as opposed to Mimics Medical (maxillofacial, orthopedic and cardiovascular applications), ISP CaseDesigner (craniomaxillofacial including soft tissue) and AccuPlan (maxillofacial).
8. MirrorMe3D System starts with the input of 3D medical imaging of soft tissue, while the other devices start with files that must be segmented prior to 3D modeling.

MirrorMe3D believes its Modeling System is safe and effective and that it is substantially equivalent to legally marketed devices. The MirrorMe3D System has the same intended use as Mimics Medical, ISP CaseDesigner and the AccuPlan Systems. The differences in technical characteristics do not add any questions of safety or effectiveness to the subject device.

G. SUMMARY OF PERFORMANCE TESTING

MirrorMe3D's Modeling System consists of patient-specific output so to provide objective evidence that the system conforms to specifications and is fit for its intended use, MirrorMe3D intends to show that every product is tested to meet acceptance criteria and we periodically audit the processes. MirrorMe3D has tried to identify the risks associated with every step of the design and manufacture process and to mitigate all of those risks.

1. Testing For each device, MirrorMe3D checks the integrity of the input imaging data, validates the visualization of the patient specific treatment options

through doctor and staff review, conducts testing and a verification of the model design files, and visually inspections all physical products using a quality protocol. The approval of the design of the anatomic model depicting the intended treatment outcome by the Doctor is required and indicates design acceptance. The model production process is tested on a monthly basis to confirm the additively manufactured outputs meet conformance standards and maintain geometric accuracy within an established tolerance range.

2. Biocompatibility and Sterilization: The models are not sterile and are not intended for any physical contact with the patient during the procedure.

3. Off-The-Shelf Software: MirrorMe3D uses only off-the-shelf software programs to design and manufacture its products. Software testing is periodically conducted to determine if the modeling maintains acceptable tolerances and is within reasonable measurement parameters and documentation was provided as recommended by the FDA Guidance for "Off-The-Shelf Software Use in Medical Devices" issued September 27, 2019. MirrorMe3D has analyzed the risks and determined that the severity of the harm that could result from a software failure is a minor level of hazard to patients.

Summary

The intention of these tests is to provide objective evidence that the system conforms to specifications, is fit for its intended use, and that its performance is substantially equivalent to the predicate device. All validations, verifications and testing demonstrate that MirrorMe3D has identified and evaluated the potential risks, and its design and production processes have been conformed to meet its quality standards.

The MirrorMe3D Modeling System is substantially equivalent to and has the same intended use as Mimics Medical but different target areas, as well as slightly different technological characteristics that do not raise different questions of safety and effectiveness, and the information submitted herein demonstrates that the system is as safe as the legally marketed predicate device.