September 30, 2022

3D LifePrints UK Ltd.
℅ Sam Murray
Principal Consultant
Olympus Regulatory Solutions
5 Seaconnet Ave
Portsmouth, Rhode Island 02871

Re: K220366
Trade/Device Name: EmbedMed
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: August 30, 2022
Received: September 1, 2022

Dear Sam Murray:

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,

Michael E. Adjodha, M.ChE.
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
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)*
K220366

Device Name
EmbedMed

Indications for Use *(Describe)*
EmbedMed 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 system, and the result is an output data file. This file may then be provided as digital models or used an input to an additive manufacturing portion of the system. The additive manufacturing portion of the system produces physical outputs including anatomical models and surgical guides for use in maxillofacial surgeries. EmbedMed is also intended as a pre-operative software tool for simulating/evaluating surgical 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.

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5. 510(K) SUMMARY K220366

This 510(k) Summary is in accordance with the requirements of the Safe Medical Device Act (SMDA) of 1990. The content of this 510(k) summary is provided in conformance with 21 CFR § 807.92.

5.1. Submitter's Information

Name:	3D LifePrints UK Ltd.
Address:	The Innovation Hub, Alder Hey Children's NHS Foundation Trust, Eaton Road West Derby, Liverpool Merseyside, England, L12 2AP United Kingdom
Phone:	+44 15152 86830
Contact Person:	Henry Pinchbeck CEO
Preparation Date:	29 September 2022

5.2. Device Name

Trade Name:	EmbedMed™
Common Name:	System for the creation of patient specific anatomical models and surgical guides
Classification Name:	Bone Cutting Instruments and Accessories
Regulation	21 CFR § 872.4120
Regulatory Class:	Class II
Product Code	DZJ, LLZ

5.3. Legally Marketed Predicate Device

CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K201353)

5.4. Device Description

EmbedMed utilizes Commercial Off-The-Shelf (COTS) software to manipulate 3D medical images to create digital and additive manufactured, patient-specific physical anatomical models and surgical guides for use in surgical procedures.

Imaging data files are obtained from the surgeons for treatment planning and various patient-specific products that are manufactured with biocompatible photopolymer resins using additive manufacturing (stereolithography).

5.4.1. Brief Written Description of the Device

EmbedMed receives patient specific medical imaging files from the prescribing clinician which is then then further processed. The processing includes a software program to segment the image file from 3D medical scan images and creates a patient-specific digital output. The digital output is then reviewed and approved by the prescribing clinician prior to delivery of the final outputs (physical or digital). A trained 3D LifePrints employee utilizes additive manufacturing (3D printing, SLA) to manufacture physical outputs which include anatomical models and surgical guides for use in maxillofacial surgeries. All outputs are provided non-sterile. All surgical guides are provided with the steps for sterilization prior to use in surgery. Anatomical models may also be provided with the steps for sterilization. The outputs of the subject device include:

- Anatomical models are physical replicas used to aid in surgical planning. They are intended to be used in conjunction with other diagnostic tools and expert clinical judgement. Anatomical models are not intended to come into contact with the patient or Surgical Guide
- Surgical Guides are used in surgical procedures to aid in bone cutting, bone marking, or bone repositioning. Drill sleeves are recommended to be used with the drilling guides. Clinicians use these cutting guides as they aid in cutting, by marking the angle and plane

Table 1: Output Device Descriptions

Output Device	Model/Design Type Examples	Mechanism of Action/Narrative Description
Surgical Guide	Jaw Cutting Guide	Guides with positional indicators, cutting planes and/or drilling holes that are affixed to patients during surgery to determine the locations and angles of osteotomies on the mandible and/or maxilla
	Orthognathic Splint	Guides that rest upon the patient's teeth during surgery to reposition the maxilla and/or mandible during orthognathic surgery
	Orthognathic Guide	Guides with positional indicators, cutting planes and drilling holes which are affixed to patients during surgery to indicate angle and location of osteotomy facilitating repositioning of the maxilla and mandible during orthognathic surgery
Anatomical Model	Sterilizable physical replica model	Physical representation of patients' facial anatomy and pathology used for the planning of maxillofacial surgeries (e.g. reconstructive, TMJ, resection, orbital, mid-face, dental, orthognathic, cosmetic). The models are used to better understand the anatomy, for decision making, reference, implant sizing, simulation etc. and that are intended to be sterilized so they can be used within an the operating theater
	Non-sterilizable physical replica model	Physical representation of patients' facial anatomy and pathology used for the planning of maxillofacial surgeries (e.g. reconstructive, TMJ, resection, orbital, mid-face, dental, orthognathic, cosmetic). The models are used to better understand the anatomy, for decision making, reference, implant sizing, simulation etc.

Output Device	Model/Design Type Examples	Mechanism of Action/Narrative Description
Digital Model	Digital replica anatomical model	Digital representation of patients' facial anatomy and pathology used for the planning of maxillofacial surgeries (e.g., reconstructive, TMJ, resection, orbital, mid-face, dental, orthognathic, cosmetic). The models are used to better understand the anatomy, for decision making, reference, implant sizing, simulation etc.

The Surgical Guides are compatible with legally marketed bone screws and compatible metal sleeves

5.4.2. Materials of Use

EmbedMed physical outputs are additively manufactured by SLA utilizing medical-grade, acrylate-based photopolymers.

5.5. Intended Use

EmbedMed 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 system, and the result is an output data file that is then used as input to an additive manufacturing portion of the system. The additive manufacturing portion of the system produces physical outputs including anatomical models and surgical guides.

Anatomical models are intended to be physical replicas used for to aid in surgical planning. They are intended to be used in conjunction with other diagnostic tools and expert clinical judgment. Surgical Guides are intended to be used in surgical procedures where they aid in bone cutting, bone marking, or bone repositioning.

5.6. Indications for Use

EmbedMed 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 system, and the result is an output data file. This file may then be provided as digital models or used an input to an additive manufacturing portion of the system. The additive manufacturing portion of the system produces physical outputs including anatomical models and surgical guides for use in maxillofacial surgeries. EmbedMed is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

5.7. Substantial Equivalence Discussion

A comparison of the similarities and differences between EmbedMed and predicate devices are provided in Table 2.

Table 2: Predicate Comparison

Specification/ Characteristic	Subject Device	Predicate Device	Comparison
	EmbedMed (K220366)	**CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K201353)**	
Classification	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	21 CFR 872.4120, Class II 21 CFR 892.2050, Class II	Identical
Product Code	DZJ, LLZ	DZJ, LLZ	Identical
Indications for Use	EmbedMed 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 system, and the result is an output data file. This file may then be provided as digital models or used an input to an additive manufacturing portion of the system. The additive manufacturing portion of the system produces physical outputs including anatomical models and surgical guides for use in maxillofacial surgeries. EmbedMed is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	CenterMed Patient Matched Assisted Surgical Planning (ASP) 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 ASP system and the result is an output data file. This file 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, surgical splints and surgical planning case reports for use in maxillofacial surgery. CenterMed Patient Matched ASP System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	Identical

Specification/ Characteristic	Subject Device	Predicate Device	Comparison
	EmbedMed (K220366)	**CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K201353)**	
Contraindications	1. Significant changes to the patient's anatomy have occurred since the medical scan used for planning purposes was obtained. 2. Hypersensitivity to acrylate resins.	1. Active infections (obvious, or clinically apparent). 2. Hypersensitivity to foreign bodies. 3. Circulatory problems, systematic diseases, or metabolic disorders. 4. Insufficient or inadequate bone tissue. 5. Secondary diseases such as degenerative processes that may have negative influences. 6. Interventions carried out in a non-sterile environment 7. Regions exposed to inappropriate forces or excessive weight loads 8. Patients unwilling to follow instructions during the postoperative phase due to their mental, neurological, or physical condition. 9. Obvious drug or alcohol abuse 10. Significant changes to the patient's anatomy have occurred since the medical scan used for planning purposes was obtained.	Substantially Equivalent
Clinical Application	Maxillofacial Surgeries	Maxillofacial Surgeries	Identical
Inputs	CT, CBCT, MRI, PET, DICOM images or CBCT of mouth/teeth) if applicable, Patients' digital photos if applicable	CT, CBCT DICOM images, Teeth models (stone models, STL file or CBCT of mouth/teeth) if applicable, Patients' digital photos if applicable	Identical
Segmentation Software	Simpleware Scan IP	Materialise Mimics	Substantially Equivalent
Outputs	Anatomical Models, Surgical Guides, Digital Models	Anatomical models, Surgical splints, Surgical guides, Surgical planning case reports	Substantially Equivalent
Materials	Anatomical models: Medical Grade Resin, acrylate Surgical guides: Medical Grade Resin, acrylate Sleeve: Medical Grade Stainless Steel or Titanium	Anatomical models: Medical Grade Polyamide (PA-12) Surgical guides: Medical Grade Polyamide (PA-12) Sleeve: Medical Grade Stainless Steel 316L	Substantially Equivalent
Manufacturing Method	3D printing (additive)	3D printing (additive)	Identical
Patient Specific	Yes	Yes	Identical
Provided Sterile	No	No	Identical

Specification/ Characteristic	Subject Device	Predicate Device	Comparison
	EmbedMed (K220366)	CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K201353)	
Sterilization Method	Steam Sterilization	Steam Sterilization	Identical
Provided Single Use	Yes	Yes	Identical
Recommended Temporary fixation style	Drill free	Drill-Free, Tapping-Free	Substantially Equivalent

5.7.1. Statement on Substantial Equivalence

EmbedMed is substantially equivalent to the legally marketed predicate device CenterMed Patient Matched Assisted Surgical Planning (ASP) System (K201353) with respect to intended use, design, materials, performance, and labeling.

5.8. Performance Data

Testing as described below has been performed to demonstrate the outputs of the EmbedMed manufacturing process conforms to the device specifications.

Testing performed and documented in this submission was also in accordance with FDA Guidance Document *Technical Considerations for Additive Manufactured Medical Devices* (December 5th, 2017).

5.8.1. Biocompatibility Testing

EmbedMed was evaluated for the overall biological safety giving consideration to the following: type of patient contact and intended clinical use, potential hazards associated with the material of construction, biocompatibility data available on the 3D-printed raw material, the history of clinical use of the material of construction, manufacturing process information, and other information available according to ISO 10993-1:2018, *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*, and FDA Guidance Document *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process."* Endpoints assessed include: cytotoxicity, sensitization, irritation, acute systemic toxicity, and material-mediated pyrogenicity.

The results of the biological risk assessment and endpoint testing confirm biocompatibility. EmbedMed is considered to meet the requirements of ISO 10993-1:2018, ISO 14971:2019, and FDA Guidance Document *Use of International Standard ISO 10993-1:2016*, for an implant device that has short term (≤ 24 hours) contact with tissue and bone.

5.8.2. Sterilization Validation

The physical outputs of the subject device including the surgical guides and anatomical models are intended to be sterilized by the end user prior to use. The sterilization process was validated using the over-kill method according to ISO 17665-1: *Sterilization of health care products – Moist heat -- Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices*. The sterilization cycle identified in the Instructions for Use were validated to a sterility assurance level (SAL) of 10^{-6}. Drying time validation was also conducted.

5.8.3. Verification and Validation Testing

The performance testing performed on EmbedMed were conducted as part of formal design verification and validation. The testing confirmed EmbedMed physical outputs meet the requirements across the range of possible patient-specific devices. Testing included:

- Installation, Operational, and Performance Qualification
- Feature Accuracy

- Dimensional Accuracy
- Simulated Use Testing

5.8.4. Clinical Studies

Clinical testing was not necessary for the demonstration of substantial equivalence.

5.9. Conclusions

EmbedMed has the same intended use and similar technological characteristics as the predicate device. Minor differences have been addressed by verification and validation testing. The testing demonstrates the subject device is substantially equivalent to the predicate device