February 1, 2023

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

Re: K221943
Trade/Device Name: EmbedMed
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF, LLZ
Dated: July 1, 2022
Received: July 5, 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,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K221943

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 the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for the appendicular skeleton. 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY K221943

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.

Submitter's Information

Name:	3D LifePrints UK Ltd.
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Phone:	+44 15152 86830
Contact Person:	Henry Pinchbeck CEO
Preparation Date:	27 December 2022

Device Name

Trade Name:	EmbedMed™
Common Name:	Orthopedic surgical planning and instrument guides
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Regulation Number	21 CFR § 888.3030
Regulatory Class:	Class II
Product Code	PBF, LLZ

Legally Marketed Predicate Device

Primary: 3D-Cut (K212237)

Reference: Fine Osteotomy (K193614)

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 non-joint replacing orthopedic surgical procedures for the appendicular skeleton.

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).

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 non-joint replacing orthopedic surgical procedures for the appendicular skeleton. 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.

Materials of Use

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

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 diagnostic purposes and 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.

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 the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for the

appendicular skeleton. EmbedMed is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

Substantial Equivalence Discussion

A comparison of the similarities and differences between EmbedMed and predicate devices are provided in the table below.

Predicate Comparison

Specification/ Characteristic	Subject Device	Primary Predicate Device	Reference Predicate Device	Comparison
	EmbedMed (K221943)	3D-Cut (K212237)	Fine Osteotomy (K193614)	
Classification	21 CFR 888.3030 (Primary), Class II 21 CFR 892.2050, Class II	21 CFR 888.3030, Class II	21 CFR 888.3030, Class II	Same
Product Code	PBF, LLZ	PBF	HRS, HWC, PBF	Same

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 the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for the appendicular skeleton. EmbedMed is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.	The 3D-Cut is intended to be used as a surgical instrument to assist in preoperative planning and/or in guiding the marking of bone and/or in guiding surgical instruments in non-acute, non-joint replacing osteotomies, including the resection of bone tumors, for femur, tibia and pelvis including sacrum.	Fine Osteotomy is a system intended for osteotomies, treatment of bone and joint deformities, fixation of fractures and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur and proximal tibia. Specifically, - The Fine Osteotomy tibial plates are indicated for open- and closed-wedge osteotomies of the medial proximal tibia, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the proximal tibia. - The Fine Osteotomy femoral plates are indicated for open- and closed wedge osteotomies of the medial and lateral distal femur, treatment of bone and joint deformities, fractures, non-unions, and malalignment caused by injury or disease, such as osteoarthritis, of the distal femur. - Fine Osteotomy instrument guides are intended to assist in pre-operative planning and/or in guiding the marking of bone and/or guiding of surgical instruments in non-acute, non-joint replacing osteotomies around the knee.	Substantially Equivalent

Specification/ Characteristic	Subject Device EmbedMed (K221943)	Primary Predicate Device 3D-Cut (K212237)	Reference Predicate Device Fine Osteotomy (K193614)	Comparison
			Fine Osteotomy is a patient-specific device.	
Clinical Application	Orthopedic Surgeries	Orthopedic Surgeries	Orthopedic Surgeries	Same
Inputs	CT, MRI, DICOM	CT, MRI, DICOM	CT, X-ray	Same
Segmentation Software	Simpleware Scan IP	ITK-SNAP/Proprietary	Unknown	Substantially Equivalent
Outputs	Anatomical Models, Surgical Guides, Surgical planning case reports	Cutting/Marking Guides	Surgical Plates, Surgical Guides	Same
Materials	Anatomical models: Medical Grade Resin, acrylate Surgical guides: Medical Grade Resin, acrylate	Cutting/Marking Guides: Polyamide	Surgical Plates: Ti-6Al-4V Cutting/Marking Guides: Polyamide (Nylon-12)	Substantially Equivalent
Manufacturing Method	3D printing (Additive)	3D Printing (Additive)	3D Printing (Additive)	Same
Patient Specific	Yes	Yes	Yes	Same
Provided Sterile	No	Unknown	No	Same
Sterilization Method	Steam Sterilization	Steam Sterilization	Steam Sterilization	Same
Provided Single Use	Yes	Yes	Yes	Same
Recommended Temporary fixation style	Drill free	Drill free	Unknown	Same

Statement on Substantial Equivalence

EmbedMed is substantially equivalent to the legally marketed predicate device 3D-Cut (K212237) with respect to intended use, design, materials, performance, safety, effectiveness, labeling and all other applicable characteristics.

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).

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."*

The results of the biological risk assessment and endpoint testing confirm any associated biological safety risks are negligible. 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.

Verification and Validation Testing

The performance testing performed on EmbedMed were conducted as part of formal design verification and validation. Verification testing performed on coupons, which were designed with the worst-case features and dimensions, demonstrated that the EmbedMed physical outputs meets the feature and dimensional accuracy requirements for patient-specific surgical guides and anatomical models.

The validation testing on the EmbedMed physical outputs manufactured from real patient scan data demonstrated through simulated use testing that the system produces patient-specific outputs that meet the intended use of the product and its design requirements. The testing confirmed EmbedMed physical outputs meet the requirements across the range of possible patient-specific devices.

Clinical Studies

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

Conclusion

EmbedMed has the same intended use and similar technological characteristics as the predicate device. Minor differences have been addressed by verification and validation testing and do not raise questions of safety and effectiveness, demonstrating the subject device is as safe, as effective, and performs as well as or better than the predicate device