TECHFIT Digital Surgery, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite 510k
SAINT PAUL MN 55114

January 6, 2023

Re: K222577
Trade/Device Name: TECHFIT Diagnostic Models
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 1, 2022
Received: November 2, 2022

Dear Prithul Bom:

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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological ImagingDevices
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K222577

Device Name
TECHFIT Diagnostic Models

Indications for Use *(Describe)*
The TECHFIT Diagnostic Models are patient-specific devices intended to be used as a pre-operative planning tool for treatment in the field of maxillofacial surgery.

The input data file (DICOM imaging information from a medical scanner file) is processed by commercial off-the-shelf software, and the result is an output data file that may then be provided as digital models or used as input to produce physical anatomic models using additive manufacturing.

The physical replica can be used for diagnostic purposes in the field of, maxillofacial applications.

TECHFIT Diagnostic Models should be used in conjunction with other diagnostic tools and expert clinical judgment.

TECHFIT Diagnostic  Models are not intended to enter the operating room

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.***

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**510(k) Summary**
**K222577**

**21 CFR 807.92 2050**

***Submitter information:***

| | |
|---|---|
| Submitter | TECHFIT Digital Surgery Inc.<br>1511 Aviation Center Pkwy<br>Suite 220H<br>Daytona Beach, FL 32114 |
| Contact person | David García-Patiño<br>Regulatory Affairs Specialist<br>Phone: +57 604 322-33-75 Ext. 165<br>david.garcia@techfit.com.co |
| Date prepared | January 6, 2023 |

***Subject device information:***

| | |
|---|---|
| Trade name | TECHFIT Diagnostic Models |
| Common or Usual name | Medical image management and processing system |
| Classification name | System, Image Processing, Radiological |
| Product code (classification regulation) | LLZ |
| Regulation number | 892.2050 |

***Predicate device information:***

| | |
|---|---|
| Trade name | Materialise N.V. |
| 510(k) number | K183105 |
| Common or Usual name | Mimics Medical |
| Classification name | System, Image Processing, Radiological |
| Product code (classification regulation) | LLZ |
| Regulation number | 892.2050 |

***Device description***

TECHFIT Diagnostic Models are virtual and additive manufactured anatomic models intended for diagnostic use during maxillofacial surgery planning.

The models are created from a CT scan of the patient's anatomy, which is segmented through Commercial-Off-The-Shelf (COTS) software and converted into virtual 3D models. The surgeon uses these 3D models to make the initial plan/diagnosis based on examination or physical measurement of the patient´s anatomy, this includes planning anatomic structures movements (for example, maxilla and mandible movements for occlusion), the resections, measurement of anatomic distances (e.g., the facial symmetry), and determining fixation points and the size and shape of the implants if requested. These functions are those that the surgeon can perform, not functions that the subject device provides by itself.

TECHFIT creates a design proposal for the case based on the information given by the medical professional and the process continues until the final design proposal is approved. Finally, the digital file can be used as an input to produce physical anatomic models through additive manufacturing.

TECHFIT Diagnostic Models are intended for single use only.

| | |
|---|---|
| ***Indications for Use*** | The TECHFIT Diagnostic Models are patient-specific devices intended to be used as a pre-operative planning tool for treatment in the field of maxillofacial surgery.<br><br>The input data file (DICOM imaging information from a medical scanner file) is processed by commercial off-the-shelf software, and the result is an output data file that may then be provided as digital models or used as input to produce physical anatomic models using additive manufacturing.<br><br>The physical replica can be used for diagnostic purposes in the field of, maxillofacial applications.<br><br>TECHFIT Diagnostic Models should be used in conjunction with other diagnostic tools and expert clinical judgment.<br><br>TECHFIT Diagnostic Models are not intended to enter the operating room |

***Device design and manufacturing***

Starting from a patient's CT scan and dentition data (optional), a virtual model of the patient's anatomy is generated. Prior to the surgery, a biomedical engineer works along with the surgeon to define a pre-operative surgical plan based on virtual 3D models of the patient's anatomy.

Based on the pre-operative plan, models are designed using medical CAD software. After the surgeon approves the pre-operative plan and device designs, the diagnostic models are produced through an additive manufacturing process

***Technological Characteristics & Substantial Equivalence Discussion***

The intended use of the subject device, TECHFIT Diagnostic Models, is the same as the predicate device, Mimics Medical (K183105). The design process for both the subject and the predicate device starts from a patient's CT scan, taken according to a specific CT scan protocol.

***Similarities to predicate***

The subject and the predicate device have the same intended use, the anatomic models are produced from the patient´s CT scan and we use the same segmentation/3D reconstruction software to create 3D anatomic models Mimics Medical (K183105).

***Differences from predicate***

The differences between the subject and predicate device are that the anatomic models are created by TechFit versus the end user.

A device comparison table of the subject and predicate device is provided in Table 1.

*Table 1. Substantial Equivalence Comparison.*

| **Characteristic** | **Subject device: TECHFIT Diagnostic models** | **Mimics Medical K183105** |
|---|---|---|
| Classification | 21 CFR 892.2050 | 21 CFR 892.2050 |
| Class | Class II. | Class II. |
| Product code | LLZ | LLZ |
| Indications for Use | The TECHFIT Diagnostic Models are patient-specific devices intended to be used as a pre-operative planning tool for treatment in the field of maxillofacial surgery.<br><br>The input data file (DICOM imaging information from a medical scanner file) is processed by commercial off-the-shelf software, and the result is an output data file that may then be provided as digital models or used as input to produce physical anatomic models using additive manufacturing.<br><br>The physical replica can be used for diagnostic purposes in the field of, maxillofacial applications.<br><br>TECHFIT Diagnostic Models should be used in conjunction with other diagnostic tools and expert clinical judgment.<br><br>TECHFIT Diagnostic Models are not intended to enter the operating room. | 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.<br><br>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. |
| Material(s) | Clear resin | Multiple |
| Manufacturer | TECHFIT Digital Surgery | Materialise N.V. |

| | | |
|---|---|---|
| Hardware Technologies | 3D Printing to produce physical output devices | 3D Printing to produce physical output devices |
| Proprietary planning software | No, we use Mimics Medical (K183105) | Yes |
| Patient-specific configuration? | Yes | Yes |
| CT Scan | Yes | Yes |
| Physician Interaction | Yes | Yes |

***Non-clinical Performance Data***

A table with the summary of the performance data was provided in Table 2

*Table 2 Summary of data performance*

| Test Performed | Description | Results |
|---|---|---|
| *3D Printing process validation* | A manufacturing process characterization was performed to validate that the manufacturing process can correctly print the TECHFIT Diagnostic Models.<br>The process validation strategy included the Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ). | The acceptance criteria were met |
| *Dimensional Validation* | The 3D printed devices were manufactured and scanned with CT scan. The 3D printed devices consisted of multiple anatomic models from different patients (mandibles and maxilla) as the worst-case to evaluate the accuracy.<br>The original model and | All the measurements complied with the acceptance criterion |

| | | |
|---|---|---|
| | scanned model were digitally aligned and overlapped. Then, the dimensional error was estimated by comparing the difference between the overlapped images on a point-by-point basis. | |
| *Packaging Validation* | The packaging system was subjected to simulated shipment following the Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169-16), and environmental conditioning as per ISTA 3A. | The acceptance criteria were met |
| *Diagnostic Qualitative Evaluation* | A clinician review report was performed with the intention to evaluate the diagnostically significance of TECHFIT Diagnostic Models (TDMs) according to the clinical experience of maxillofacial surgeons | The interviewed surgeons deemed TECHFIT Diagnostic models a significant help when it comes to identifying different pathologies and plan a more precise surgical intervention when used in conjunction of other diagnostic tools. |
| *Fidelity Validation of detectable anatomical landmarks* | A test was performed to validate the device´s replicability of anatomical landmarks from educational anatomic models and maintain dimensional accuracy. | All selected landmarks in the educational anatomic model were identified in the virtual models and the 3D printed models |

***Substantial Equivalence Conclusion***

Based on the indications for use, technological characteristic, and comparison to subject/predicate devices, the TECHFIT Diagnostic Models show to be substantially equivalent to the predicate device.