November 4, 2020

ProtoMED, Inc.
Rick Miller
Director of Quality
1329 W 121st Ave
Westminster, Colorado 80234

Re: K193499
Trade/Device Name: DigiGuide System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument and Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: October 2, 2020
Received: October 5, 2020

Dear Rick Miller:

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 Srinivas “Nandu” Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193499

Device Name
DigiGuide System

Indications for Use *(Describe)*
The ProtoMED DigiGuide 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 DigiGuide System and the result is an output data file that is used as the input to a rapid prototyping portion of the system that produces physical outputs including templates for use in maxillofacial surgery. The DigiGuide System 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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Traditional 510(k) Notification for the ProtoMED DigiGuide System

510(k) SUMMARY

K193499

MANUFACTURER INFORMATION

Company Name: ProtoMED, Inc.
Company Address: 1329 West 121st Westminster, CO 80234 USA
Company Phone: (303) 466-5610
Company Contact: Richard Miller

PREPARATION DATE

November 2nd, 2020

DEVICE IDENTIFICATION

Device Trade Name: DigiGuide System
Device Common Name: DigiGuide System
Classification Name: Bone cutting instrument and accessories
Regulation Number: 21 CFR 872.4120
Product Code: DZJ, LLZ
Device Class: Class II
Classification Panel: Dental

PREDICATE/REFERENCE DEVICES

Predicate: Medical Modeling, Inc. VSP System (K133907)
Reference: KLS Martin Individual Patient Solutions (K180962)

DEVICE DESCRIPTION

System Overview:
The ProtoMED DigiGuide System consists of a digital surgical plan (DigiPlan), applicable DigiGuide Templates, and optional anatomical models in order to plan and implement a maxillofacial surgery.

DigiPlans:
A DigiPlan uses CT scans of patient anatomy and other patient data to create a computer based surgical simulation under the direction of a physician in conjunction with company technicians. The output is a report that represents the execution of that simulation at intraoperative and final conditions. The report may also include documentation of required osteotomies, cephalometric data if applicable, anatomy movements or details of any DigiGuide templates or Anatomical Models that will be used to support the surgical implementation.

Anatomical Models:
Anatomical models are physical representations of patient anatomy in a CT-scanned or DigiPlan (modified) position. Physical models are patient-specific and fabricated from a non-sterilizable polymer using an additive manufacturing process. Digital anatomical models are provided in STL or DICOM format for use to aid the physician in surgical planning and to provide a visual aid.

Anatomical models are for informational purpose only and do not have interaction or contact with the patient, device, or surgical field.

DigiGuide Templates:
DigiGuide Templates are patient-specific devices that register to anatomy that support a DigiPlan such as teeth arches or bony segments, direct planned osteotomies, and inspect the results of planned procedures. Templates are produced using an additive manufacturing process and are provided non-sterile. See Table 1 below for individual template functions and details. Design features may include:

1. Inverse images of anatomy in intended application position.
2. Mounting holes designed to secure templates to anatomy if needed.
3. Partial or complete palatal support for maxillary surgeries.
4. Bars, tabs, holes, or slots that indicate the position and direction of osteotomies and movements.
5. Stiffening elements.
6. Labels or other indicators.

The system may require (but does not include) FDA cleared fastening hardware (i.e. bone plates, bone screws, pins) that must be obtained by the physician from other sources prior to initiating the surgical procedure.

DigiGuide System patient-specific templates are solely intended to be designed and manufactured within the ProtoMED facility only, using manufacturing controls developed and validated by ProtoMED.

Table 1: DigiGuide Template Functions and Details

	Occlusal		**Marking**	**Placement**	**Inspection**
	Intraoperative	**Final**			
Nature of Body Contact Category	External Communicating Device				
Nature of Body Contact Type	Mucosal membrane (teeth/palette/gum tissue also)		Tissue/Bone		
Contact Duration	Limited (less than 24 hours)	Prolonged (up to 30 days)	Limited (less than 24 hours)		

- Occlusal Templates: Register jaws in relation to each other to achieve the desired intermediate and/or final positions, as well as provide stability during the healing process (final template only). The final template may be used up to 30 days after surgery for stability during the healing process.
- Marking Templates: Indicate the location/orientation of osteotomies or screw holes. Templates are placed directly on exposed bone to mark osteotomy and/or hole locations, then removed prior to performing cuts or drills.
- Placement Templates: Position and hold anatomy into the planned occlusion or position, allowing the physician to fixate any required permanent placement hardware such as bone plates (not included in the DigiGuide System), then removed and discarded.
- Inspection Templates: Verify that the osteotomies were performed as planned and/or the appropriate amount of bony anatomy was removed.

Templates are not intended to be in place while cuts or drills are applied.

INDICATIONS FOR USE

The ProtoMED DigiGuide 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 DigiGuide System and the result is an output data file that is used as the input to a rapid prototyping portion of the system that produces physical outputs including templates for use in maxillofacial surgery. The DigiGuide System is also intended as a pre-operative software tool for simulating/evaluating surgical treatment options.

INTENDED USE

The DigiGuide System is intended to be used on adult patients as follows:

1. A digital surgical plan (DigiPlan) is developed by company technicians with the collaboration of the involved physician as follows:
    a) A CT scan or physical representation of a patient's bony anatomy is translated into a set of 3D objects in STL format using medical image processing software.
    b) The STL models of the patient's teeth are integrated with the then-bony anatomy as needed.
    c) Indicated osteotomies are performed in digital space and cephalometric landmarks are established.
    d) Various sections of maxillofacial bony anatomy are virtually moved to a desired location by either written instruction or during a live, online meeting with ProtoMED engineers, technicians, and the physician.
    e) The resulting set of STL objects represents the anatomy in the final position and a set of measurements that both indicate the proposed cephalometric position and identify relative movements of all of the objects.
2. DigiGuide Templates are created from the inverse images of the anatomy with added alignment and/or support structures.
    a) Biocompatible polymers are used to additively manufacture all templates.
    b) Templates must be sterilized according to instructions provided before use in surgery.
    c) Templates may be temporarily affixed to the patient to assist in the transfer of the DigiPlan from computer space to the patient.
    d) Templates are not implanted and do not include any fastening hardware.
    e) Templates must be removed from the patient prior to the end of the surgery, except for the final DigiGuide occlusal templates, as required by the surgeon. If remaining affixed to the patient following surgery, they must not be affixed for more than 30 days after surgery.
    f) After removal, all templates are disposed with local biohazardous disposal procedures.
3. Anatomical models are physical or electronic (STL) models of patient anatomy in the CT scanned or DigiPlan position.
    a) Physical models are additively manufactured and may be used as physical references to design planning and as a visual aid.
    b) STL models are representations of CT scan anatomy or anatomy changes resulting from a DigiPlan.
    c) Anatomical models are for informational purpose only and do not have interaction or contact with the patient, device, or surgical field.

COMPARISON TO PREDICATE DEVICES

The intended use of the DigiGuide System and its predicate device, Medical Modeling VSP System (K133907), are substantially equivalent as discussed below. Table 2 compares the DigiGuide System to both the predicate device and reference device KLS Martin Individual Patient Solutions (K180962).

1. The DigiGuide System employs substantially equivalent fundamental technologies as the identified predicate including:
    a) The application of commercial Off-The Shelf (COTS) Software for image transfer, manipulation, and surgical planning,
    b) Material and manufacturing of patient-specific templates.
2. Both of the systems are intended to facilitate maxillofacial procedures by producing patient-specific anatomical models, surgical positioning and osteotomy templates, and case reports.
3. Both require the development of digital surgical plans by trained personnel with active support from the physician.
4. Both require the fabrication of surgical components from a physician-approved digital plan in an additive manufacturing environment.

5. Both are patient-specific devices.
6. Both are single-use devices.
7. Both provide non-sterile templates which require sterilization to SAL $1x10^{-6}$ by the end user (physician).
8. Both utilize metal sleeve inserts to eliminate hardware interaction during fixation with bone screws.
9. The DigiGuide System has substantially equivalent technical characteristics to the predicate device, including:
    a) System Inputs: Images from medical scanners (i.e., CT) or physical data (i.e. stone teeth models)
    b) System Outputs: Physical outputs such as patient-specific anatomical models, surgical positioning and osteotomy templates, and case reports
    c) Materials used in Physical Outputs: Biocompatible polymers and surgical grade stainless steel
10. Differences between the DigiGuide System and its predicate device include:
    a) The predicate system includes surgical guides intended to remain affixed to the patient to guide cutting tools. The DigiGuide System does not provide these surgical (or cutting) guides. The templates provided by the DigiGuide System are only intended to mark where the cuts are to be applied. The DigiGuide System is substantially equivalent to the predicate since both result in identifying the proper drilling and cutting location(s). The predicate device uses "patient-specific" in the Summary of the predicate device submission. Thus, the DigiGuide System is substantially equivalent to the predicate device.
    b) The predicate system uses a surgical grade stainless steel sleeve insert, whereas the DigiGuide System and the reference device both utilize a titanium surgical sleeve insert. Both metals are surgical grade, FDA-cleared materials intended to eliminate interaction between hardware and template material. Therefore, the DigiGuide System is equivalent to both the predicate and reference devices.

Table 2: Comparison to Predicate and Reference Devices

	ProtoMED, Inc.	**Medical Modeling, Inc. (Predicate Device)**	**KLS Martin (Reference Device)**
Device Name	DigiGuide System	VSP® System	Individual Patient Solutions (IPS) Planning System
510K Number	TBD	K133907	K181241
Regulatory Class	II	II	II
Classification	872.4120	872.4120, 892.2050	872.4120, 892.2050
Product Codes	DZJ, LLZ	DZJ, LLZ	DZJ, LLZ
Indications for Use	The ProtoMED DigiGuide 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 DigiGuide System and the result is an output data file that is used as the input to a rapid prototyping portion of the system that produces physical outputs including templates for use in maxillofacial surgery. The DigiGuide System is also intended as a pre-operative software tool for simulating/ evaluating surgical treatment options.	The Medical Modeling VSP® 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 VSP® System and the result is an output data file that is used as the input to a rapid prototyping portion of the system that produces physical outputs including anatomical models and templates for use in maxillofacial surgery. The VSP® System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	The KLS Martin Individual Patient Solutions (IPS) Planning 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 IPS Planning 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, guides, splints, and case reports for use in maxillofacial surgery. The IPS Planning System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.
Device Type	Patient specific	Patient specific	Patient specific
Usage	Patient-Specific, Single Use	Single Use	Patient-Specific, Single Use
Sterilization	By end user	By end user	By end user
Patient Group	Adult	Adult	Adult
Environment of Use	Surgical clinic	Surgical clinic	Surgical clinic
Device Disposition	Removed from patient	Removed from patient	Removed from patient
Template Material	Biocompatible polymers and titanium alloy	Biocompatible polymers and surgical grade stainless steel	Anatomical Models: Epoxy/Resin, Acrylic Cutting/Marking Guides: Polyamide, Titanium Alloy (Ti-6Al-4V), CP Titanium Splints: methacrylate

SUMMARY OF TESTING AND PERFORMANCE DATA

This is not an energized device. Electromagnetic Compatibility, Electrical, and Immunity testing is not applicable.

Electromagnetic Compatibility, Immunity Testing and Electrical Safety Testing are not applicable.

Verification and validation testing were performed on the planning/design process, materials, manufacturing process, and the cleaning and recommended sterilization methods of the ProtoMED DigiGuide System. The intention of these tests was 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.

Sterilization

Sterilization validation was conducted in accordance with international standard ISO 17665 and FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." to a sterility Assurance Level (SAL) of 1x10-6. All test method acceptance criteria were met.

Biocompatibility

Biocompatibility validation was conducted in accordance with international standard ISO 10993-1 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 testing adequately address biocompatibility for the output devices and their intended use. Biocompatibility testing on the final finished device included: cytotoxicity, sensitization, irritation, acute systemic toxicity, material mediated pyrogenicity, and implantation

Because the ProtoMED DigiGuide System is a combination of a manufacturing process and the patient-specific outputs of the manufacturing process (models and templates), performance testing for the device includes methods of process validation, including installation, operational, and process validations. ProtoMED determined that successful execution of the validations would be comprised of the following: 1) use STL files from patient anatomy as input for both anatomical model and template manufacturing input, 2) process the files using currently validated software versions and procedures, 3) output digital files that meet requirements, and 4) manufacture models and templates from output digital files that meet requirements.

The final output STL files and physical models/templates demonstrated dimensional and clinical equivalency to STL files used as inputs. The equivalency was demonstrated through overlay of parts for comparison analysis.

All Design, Process, and other Verification and Validation testing which were conducted as a result of risk analyses and design impact assessments, showed conformity to pre-established specifications and acceptance criteria. The acceptance criteria were established in order to demonstrate device performance and substantial equivalence of the system to predicate devices.

CONCLUSION

It is the conclusion of ProtoMED, Inc. that the DigiGuide System is substantially equivalent in intended use, materials, technological characteristics, and performance characteristics to the predicate device already on the market.