February 11, 2022

OsteoMed
Diane Rutherford
Regulatory Affairs Manager
3885 Arapaho Road
Addison, Texas 75001

Re: K212570
Trade/Device Name: OsteoPlan System
Regulation Number: 21 CFR 872.4120
Regulation Name: Bone Cutting Instrument And Accessories
Regulatory Class: Class II
Product Code: DZJ, LLZ
Dated: November 12, 2021
Received: November 15, 2021

Dear Diane Rutherford:

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)*
K212570

Device Name
OsteoPlan System

Indications for Use *(Describe)*
The OsteoPlan™ 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 OsteoPlan™ System and the result is an output data file that may then be provided as digital models or used as input to the additive manufacturing portion of the system that produces physical outputs including anatomic models and splints for use in maxillofacial surgery. The OsteoPlan 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.

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

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510(k) SUMMARY
K212570

I. SUBMITTER

OsteoMed
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Email: diane.rutherford@acumed.net
Contact Person: Diane Rutherford
Date Prepared: February 9, 2022

II. DEVICE

Name of the Device:	OsteoPlan™ System
Common or Usual Name:	Patient specific maxillofacial anatomical models, splints, and surgical plans
Classification Name:	Bone Cutting Instrument and Accessories
Classification:	Class II, 21 CFR 872.4120
Product Code:	DZJ, LLZ

III. PREDICATE DEVICES

Predicate Device: VSP® System, Medical Modeling, Inc (K133907, K120956)

Reference Device: Surgicase Guides, Materialise (K103136)

IV. DEVICE DESCRIPTION

OsteoMed uses computer aided modeling to assist the physician with planning complex maxillofacial surgeries. Specifically, the OsteoPlan™ System provides patient-specific anatomical models, splints, and patient-specific surgical plans and digital files of the surgical plan to assist physicians with maxillofacial surgeries. Outputs of the OsteoPlan™ System are designed with physician input and reviewed by the physician prior to finalization and distribution. All outputs are manufactured by OsteoMed using additive manufacturing (SLS and SLA), only with direct physician involvement to reduce the criticality of the outputs.

The system uses electronic medical images of the patient anatomy (CT and CBCT) with input from the physician to create the plan and splints for executing surgery. Off-the-shelf (OTS) software is used for surgical planning.

The outputs of the system include Orthognathic Occlusal Splints, Case Reports, and Anatomic models. The splints are offered in commonly used forms, in both intermediate and final positioning, and some are available with ligature holes.

Case reports are digital and physical documents created to lay out the surgical plan, dictated by the surgeon, and show outputs of the OsteoPlan™ system that will be used to translate the plan during surgery.

Anatomic models are tools provided to physicians for complex anatomy visualization or to pre-plan surgery with an accurate physical representation of patient anatomy. Anatomic models may include maxilla, mandible, or skull models.

V. INDICATIONS FOR USE

The OsteoPlan™ 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 OsteoPlan System and the result is an output data file that may then be provided as digital models or used as input to the additive manufacturing portion of the system that produces physical outputs including anatomic models and splints for use in maxillofacial surgery. The OsteoPlan System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The principles of operation and technological characteristics are substantially equivalent between the subject device and the primary predicate, VSP System. Specifically, the predicate device includes patient specific anatomic models and splints produced through 3D printing. The only difference in the Technological Characteristics is found in the materials of the outputs. The OsteoPlan System uses photopolymers for splints while the VSP System uses photopolymers (with stainless-steel inserts) in the cutting guides of the system. The OsteoPlan System uses Polyamide anatomic models (Polyamide 12) produced through an SLS printing process equivalent to the reference device, SurgiCase Guides (K103136), which includes outputs for the same anatomic region, made out of identical material (Polyamide 12) and printing process (SLS). The subject device contains a subset of the outputs of the predicate and reference device.

	New Device	**Primary Predicate**	**Reference Predicate**
Trade Name	**OsteoMed OsteoPlan™ System K212570**	**Medical Modeling VSP System K133907, K120956**	**Materialise Surgicase Guides K103136**
Indication for Use	The OsteoPlan™ 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 OsteoPlan System and the result is an output data file that may then be provided as digital models or used as input to the additive manufacturing portion of the system that produces physical outputs including anatomical models and splints for use in maxillofacial surgery. The OsteoPlan 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 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, templates, and surgical guides for use in maxillofacial surgery. The VSP System is also intended as a pre-operative software tool for simulating / evaluating surgical treatment options.	SurgiCase Guides are intended to be used as surgical tools to transfer a pre-operative plan to the surgery. The devices are intended to guide the marking of bone and/or guide surgical instruments in mandibular and maxillofacial surgical procedures. SurgiCase Guides are intended for single use only.
Outputs	Anatomic Models Surgical Positioning Templates (splints) Patient Specific Case Reports	Anatomical Models Surgical Positioning Templates/Guides Osteotomy Templates/Guides Patient Specific Case Reports Plate Bending Templates/Guides Stainless Steel Culling and Drill Inserts	Surgical Positioning Templates/Guides Osteotomy Templates/Guides Patient Specific Case Reports Plate Bending Templates/Guides

	New Device	Primary Predicate	Reference Predicate
Trade Name	**OsteoMed OsteoPlan™ System K212570**	**Medical Modeling VSP System K133907, K120956**	**Materialise Surgicase Guides K103136**
Additive Manufacturing	Yes	Yes	Yes
Biocompatible Materials	Yes	Yes	Yes
Patient-Contacting External Communicating Tissue/Bone/Dentin	Limited (<24 hours): Models Prolonged (24 hours -30 Days): Splints	Limited and Prolonged	Limited

VII. SUMMARY OF NON-CLINICAL TESTING

The following performance data were provided in support of the substantial equivalence determination.

Equipment/Process Qualification (IQ/OQ/PQ) was performed in accordance with the OsteoMed quality management system with all validations meeting acceptance criteria.

Software Validation and documentation for software of moderate level of concern was provided per the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" and "Off-The-Shelf Software Use in Medical Devices." All software verification/validation passed.

Cleaning Validations were performed in accordance with FDA Guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling. All testing passed.

Steam Sterilization Validation was conducted using both pouches and rigid sterilization containers in accordance with ANSI/AAMI/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

Biocompatibility testing for the worst-case splint and anatomical model was conducted per its contact classification according to the 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" Testing included: cytotoxicity, sensitization, irritation, acute toxicity, pyrogenicity, subchronic toxicity, and implantation. All biocompatibility testing passed.

Packaging Validation was conducted to confirm that the packaging for the OsteoPlan System protects and retains the splints and models during normal shipping and handling. All testing passed.

Shelf Life was established with functional testing to confirm the specified requirements were met. All testing passed.

A Cadaver Study was conducted to verify the functionality of the design of the OsteoPlan system via simulated use with all acceptance criteria being met.

Performance equivalence was shown through the verification comparison to the predicate device.

Clinical testing is not required to support substantial equivalence.

VIII. CONCLUSION

The conclusions drawn from the nonclinical tests demonstrate that the OsteoMed OsteoPlan™ System is substantially equivalent to the legally marketed device predicates.