March 16, 2020

The Methodist Hospital Research Institute
d/b/a Houston Methodist Research Institute
Christina Talley
Director, Regulatory Affairs and Translational Management
Methodist Research Institute
6670 Bertner Avenue
Houston, Texas 77030

Re: K190767
Trade/Device Name: AnatomicAligner
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture Archiving And Communications System
Regulatory Class: Class II
Product Code: LLZ
Dated: July 13, 2019
Received: July 17, 2019

Dear Christina Talley:

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.
Acting Assistant 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)*
K190767

Device Name
AnatomicAligner

Indications for Use *(Describe)*
AnatomicAligner is software for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as CT or MRI, in patients who have reached skeletal and dental maturity.

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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1 510(K) SUMMARY K190767

In accordance with 21 CFR 807.92, the following summary of the information in the 510(k) submission is provided.

1.1 807.92(A)(1)

Summary Date:	3/16/2020
Submitter:	The Methodist Hospital Research Institute d/b/a Houston Methodist Research Institute 6670 Bertner Ave. Houston, Texas 77030
Contact:	Christina Talley, MS, RAC, CCRP, CCRC. Program Director Direct: 713-363-9155 Email: ctalley@houstonmethodist.org

1.2 807.92(A)(2)

Trade Name:	**AnatomicAligner**
Common Name:	Radiology Image Processing Software
Device:	System, Image Processing, Radiological
Regulation Number:	21 CFR 892.2050
Regulation Description:	Picture Archiving and Communication System
Review Panel:	Radiology
Device Class:	Class II
Product Code:	LLZ
Indication For Use:	**AnatomicAligner** is software for pre-operative simulation of orthognathic surgical treatment options, based on imaging information from a medical scanner such as CT or MRI, in patients who have reached skeletal and dental maturity.

1.3 807.92(A)(3) – PRIMARY PREDICATE

Device Name:	**SurgiCase**, **SurgiCase CMF**, **ProPlan CMF**
Manufacturer:	Materialise N.V.
510(k) Number:	**K111641**
Product Code:	**LLZ**
Regulation Number:	21 CFR 892.2050
Regulation Description:	Picture Archiving & Communication System

1.4 807.92(A)(4) – DEVICE DESCRIPTION

Device Description:	**AnatomicAligner** is an image-processing software with a user-friendly interface for pre-operative simulation of orthognathic surgical treatment options based on imaging information from a medical scanner such as CT or MRI. The software planning results may be transferred to surgery.

1.6 807.92(A)(6) – TECHNOLOGICAL CHARACTERISTICS

1.6.1 Technological Similarities

The following table summarizes the similarities in the technological characteristics of **AnatomicAligner** and the predicate device **ProPlan**.

Technology	AnatomicAligner	ProPlan (Predicate)	Comparison
Computer	The AA software interfaces with the standard Windows PC devices including: Storage, Mouse, Keyboard, Display, and Printer.	Intel Core2Duo or equivalent; 3GB RAM; AMD Radeon or NVIDIA GeForce graphics card with 128MB RAM or equivalent.	Both products run on general purpose commercial computers.
Operating System	The AA software interfaces with the underlying Windows operating system.	Windows Vista SP2 x64 Windows 7 x64 Windows 8 x64	Both products use a general purpose commercial operating system.
Patient Images	To create a new surgical simulation, select New from the AnatomicAligner main screen. A prompt to Select a DICOM Document will be presented.	After scanning your patient, you must import the images to the PROPLAN CMF Software.	Both products use DICOM to import patient images for processing.
Segmentation and 3D reconstruction	A 3D object is created using the selected mask and applying the selected options.	The “Segmentation Wizard” will guide you step-by-step through the process of segmenting bone parts and soft tissue. The result will be a 3D object that can be used in planning wizards.	Both products provide the user software tools to segment bone and soft tissue to create 3D objects from the patient images.

Technology	AnatomicAligner	ProPlan (Predicate)	Comparison
Registration And Reorientation	Registration in AnatomicAligner is performed using Transformation and Auto-Registration tools.	The “Reposition Wizard” can be used to reposition 3D objects. Selected 3D objects can be translated. The selected 3D object can be rotated.	Both products provide the user software tools to translate and rotate 3D objects.
Cephalometric Analysis	3D Cephalometry in the AnatomicAligner is achieved by defining a cephalometric analysis scheme and digitizing landmarks for it.	The “Cephalometry Wizard” allows you to indicate anatomical landmarks on objects in the 2D or 3D view to perform a cephalometric analysis.	Both products provide the user software tools to perform a cephalometric analysis.
Virtual Osteotomy	Virtual osteotomy is used to cut a 3D bone model into two bony segments.	Different osteotomy plane types can be selected.	Both products provide the user software tools to perform an osteotomy.
Surgical Simulation	Create a Surgical Plan or orthognathic surgery.	The Orthognathics module in PROPLAN CMF Software allows you to plan Orthognathic surgeries.	Both products provide the user software tools to simulate orthognathic surgery.

1.6.2 Technological Differences

The following table summarizes the differences in the technological characteristics of **AnatomicAligner** and the predicate device **ProPlan**.

Technology	**AnatomicAligner**	**ProPlan** (Predicate)	Comparison
Graphical User Interface	2D and 3D views	2D and 3D views.	Both products provide common 2D and 3D image views and mouse controls. Differences in graphic appearance are cosmetic and raise no new questions.
Splint design	The splint design is transferred to an STL file which can be used by a 3rd party lab to manufacture the splint.	Export 3D objects as .mdck files (this proprietary file format allows you to exchange 3D objects within relevant Materialise software solutions, for e.g. opening your PROPLAN CMF Software planning file in 3-maticSTL in order to design your own guides and splints.	Both products provide a mechanism to transfer a splint design to a lab for fabrication. As an example, the STL file created by AnatomicAligner can be read and edited by 3-maticSTL. Thus, differences in file formats used to transfer the design raise no new questions.

1.7 807.92(B)(1) – NON-CLINICAL PERFORMANCE DATA

AnatomicAligner has successfully undergone extensive verification and validation testing to ensure that all requirements for the software have been met per FDA Guidance. These results provide objective evidence that the outputs of the software design activity meet all of the specified requirements for that activity. Therefore, the **AnatomicAligner** Software version 1.0 has been verified and validated as meeting all requirements.

1.8 807.92(B)(2) – CLINICAL PERFORMANCE DATA

Based on the criteria listed in FDA guidance documents, no clinical testing of **AnatomicAligner** was required or performed.

1.9 807.92(B)(3) – CONCLUSION

The intended uses of **AnatomicAligner** and **ProPlan** are the same. The technological characteristics of the **AnatomicAligner** and the predicate device **ProPlan** are very similar. Any differences are minor and do not affect a determination of substantial equivalence.

AnatomicAligner was developed under the Quality System Regulation using Design Controls 21 CFR 820.30. This included establishing and maintaining procedures to ensure design requirements are met. All elements of the process have been documented, including design and development plan, design input, design output, design review, design verification, design validation, design transfer, design changes, and design history file.

AnatomicAligner has successfully undergone extensive verification and validation testing to ensure that all requirements for the software have been met. These results provide objective evidence that the outputs of the software design activity meet all of the specified requirements for that activity. Therefore, the **AnatomicAligner** Software version 1.0 has been verified and validated as meeting all requirements.

No applicable mandatory performance standards or special controls exist for **AnatomicAligner**. The product design, development and manufacturing conform to Quality System Regulations. Results of testing and standards conformance demonstrate safety and effectiveness of **AnatomicAligner**. **We conclude that AnatomicAligner and ProPlan are substantially equivalent.**