December 22, 2020

Choice Biotech Inc.
Tyler Kuo
RD Vice President
Rm. C, 4F, No.13, Nanke 3rd Rd., Xinshi Dist.
Tainan City, 74147
Taiwan

Re: K201036
Trade/Device Name: PlaniMax Orthodontic Software
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: July 20, 2020
Received: July 27, 2020

Dear Tyler Kuo:

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 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)*
K201036

Device Name
PlaniMax

Indications for Use *(Describe)*
The PlaniMax Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the PlaniMax requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

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.

510(k) Summary

This summary of 510(k) safety and effectiveness information in accordance with the requirements of Safe Medical Device Act (SMDA) of 1990 and Title 21 CFR 807.92.
The assigned 510(k) number is K201036

Submitter:	CHOICE BIOTECH INC. Rm. C, 4F, No.13, Nanke 3rd Rd., Xinshi Dist., Tainan City 74147, Taiwan Phone: +886-6-505-7289 Fax: +886-6-505-7301
Contact Person:	Tyler Kuo / RD Vice President Email: tylerkuo@mai l.wearechoice.com Phone: +886-6-505-7289
Date Prepared:	December 21st , 2020
Proprietary Name:	PlaniMax Orthodontic Software
Common Name:	Orthodontic Plastic Bracket (Software)
CFR Classification:	21 CFR 872.5470
Device Class:	II
Product Code:	PNN
Panel:	Dental
Primary Predicate:	Ortho System from 3ShapeA/S (K171634)

Device Description:

The PlaniMax Orthodontic Software for dental retainers and dental cast for sequential aligners is a software system used for the management of3D scanned orthodontic models of the patients, orthodontic diagnosis by measuring, analyzing, inspecting and visualize 3D scanned orthodontic models , virtual planning of orthodontic treatments by simulating tooth movements , and design of orthodontic appliances based on 3D scanned orthodontic models.

Indications for Use:

The PlaniMax Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives.

The use of the PlaniMax requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.

Summary of the technological characteristics:

PlaniMax Orthodontic Software is functionally equivalent to the following predicate device: Ortho System (K171634) cleared January 17th, 2018.

The following tables demonstrates the intended uses and technical characteristics of PlaniMax Orthodontic Software are substantially equivalent to the predicate devices.

Functional Specification Comparison Table for the PlaniMax Software and Ortho System (K171634)：

Specification	PlaniMax	Ortho System (K171634)	Comparison Result
Indications for Use	The PlaniMax Orthodontic Software is indicated for use as a front-end software tool for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options, including dental casts, which may be used for sequential aligner trays or retainers. These applications are based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome i consistent with the planned/desired treatment objectives. The use of the PlaniMax requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	The 3Shape Ortho System™ is intended for use as a medical front-end device providing tools for management of orthodontic models, systematic inspection, detailed analysis, treatment simulation and virtual appliance design options (Custom Metal Bands, Export of Models, Indirect Bonding Transfer Media) based on 3D models of the patient's dentition before the start of an orthodontic treatment. It can also be applied during the treatment to inspect and analyze the progress of the treatment. It can be used at the end of the treatment to evaluate if the outcome is consistent with the planned/desired treatment objectives. The use of the Ortho System™ requires the user to have the necessary training and domain knowledge in the practice of orthodontics, as well as to have received a dedicated training in the use of the software.	Similar. Compare to the predicate device, the virtual appliance design options of PlaniMax is including dental casts, which may be used for sequential aligner trays or retainers.
Technology Features	● Stand Alone Software Module ● Imports Digital Patient Scans ● Can be used to design Dental Casts ● Useful for Diagnosis, treatment planning, and CAD design ● Virtual Planning of tooth movement ● Supports STL Files	● Stand Alone Software Module ● Imports Digital Patient Scans ● Can be used to design Dental Casts ● Useful for Diagnosis, treatment planning, and CAD design ● Virtual Planning of tooth movement ● Supports STL Files	Same.
Minimum Hardware/ Software Requirements	● OS: Windows 7 32-bit or later ● RAM: 4 GB ● Monitor Resolution: 1024 X 768 ● Video Card Memory: 1 GB ● Hard Drive Space: 100 GB ● CPU: Intel Core i3 or equivalent ● Network: Network Internet connection ● Mouse: Any Mouse with scrolling wheel or button	● OS: Windows 7, 8 or 10 64-bit ● RAM: 8 GB ● Monitor Resolution: 1280 X 800 ● Video Card Memory: 1 GB ● Hard Drive Space: 250 GB ● CPU: Intel Core i5 or equivalent ● Network: Network Internet connection ● Mouse: Any Mouse with scrolling wheel or button	Similar. No effect to the indications for use.

The PlaniMax Software has the same intended uses and technical characteristics as the Ortho

System (Kl71634):

Feature	PlaniMax	Ortho System (K171634)
Supported anatomic	Maxilla/Mandible	Maxilla/Mandible
Intended Use		
Managing Patient and case base data	Yes	Yes
Collection of study material	Yes	Yes
Alignment of study material	Yes	Yes
Measuring study material	Yes	Yes
Analyzing Study material	Yes	Yes
Treatment Simulation	Yes	Yes
Virtual Appliance Design	Yes	Yes
Managing patient and case base data		
Creating, editing, deleting and copying patient data	Yes	Yes
Creating, editin g, deleting and copying case data	Yes	Yes
Collection of study material		
Surface scan for intraoral scanner	Yes	Yes
Surface scan from STL file	Yes	Yes
CT image data (DICOM)	No	Yes
2D overlay (PNG, JPG, BMP)	Yes	Yes
Alignment of study material		
Aligning surface scan and CT image	No	Yes
Aligning Cephalometric Images	Yes	Yes
Alignment of 2D overlays	Yes	Yes
Ability to check/adjust DICOM visibility	No	Yes
DICOM scan Segmentation	No	No
Measuring study material		
2D Measurement tool box	Yes	Yes
3D Measurement tool box	Yes	Yes
Analyzing study material		
Arch shape	Yes	Yes
Wire length	Yes	Yes
Tooth width	Yes	Yes
Bolton	Yes	Yes
Space Analysis	Yes	Yes
Overjet/Overbite	Yes	Yes

Feature	PlaniMax	Ortho System (K171634)
Occlusion Map	Yes	Yes
Treatment Simulation		
2D & 3D simulation	Yes	Yes
Virtual Appliance Design		
Orthodontic Appliance Search	No	Yes
Orthodontic Appliance Virtual Preparation	Yes	Yes
Orthodontic Appliance Design	Yes	Yes
Orthodontic appliance Export	Yes	Yes

Non-Clinical Testing:

Software, hardware , and integration verification and validation testing was performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued May **11,** 2005).

The validation suite includes validation of implemented mitigations related to device hazards identified in the risk management procedures.

All test results have been reviewed and approved, showing the PlaniMax to be substantially equivalent to the reference devices.

Clinical Testing:

Clinical testing is not a requirement and has not been performed.

Conclusion:

Based on comparison of indications for use, technological features, performance testing, and software validation test results, the PlaniMax Orthodontic Software is found to be substantially equivalent to the predicate device.