CHOICE BIOTECH

CHOICE Biotech Inc.

Digital Orthodontics Solution

Clear Aligner System & Services

Choose To Be Effective

Contents

About Company

CHOICE Biotech is a "software" + "product" company and expertise in dental industry. We developed professional software for designing clear aligner and surgical guide. Other than licensing of Software as a Medical Device (SaMD) in Taiwan FDA, we have an ISO 13485:2016 certification factory in southern Science park and manufacture customized product via 3D printing. We also provide design service to customers.

CHOICE Biotech was founded by a team which has more than ten years of experience in 3D software development and dental applications. With our R&D capability and domain knowledge, we develop software and provide service to satisfy dentists' needs and improve it over time via feedbacks. We always want to perfect ourselves, not only in software development and services but also in manufacturing process and quality of our products. The company vision is to apply technologies to make a healthy and beautiful life. And our goal is to facilitate the doctors' work and make process easier and faster.

Digital Orthodontics Solution

Our self-developed orthodontic software - PlaniMax, assists doctors in digital setup, analysis and evaluation, gradually formulates customized treatment plan without difficulty.

1. Provide cloud-based storage service as a bridge between the clinical and the engineer. Users can upload patients data and information through private accounts, the projects and treatment plans will further be established according to the doctor' s indication.
2. With auto tooth segmentation function and a variety of adjustment tools, users are able to adjust and simulate bite relationship.
3. Based on traditional orthodontic theory, the algorithm simulates close-to-real clinical treatment.
4. Provide comprehensive analysis information such as tooth movement and statistics; 3D animation simulation will give patients a better picture of their treatments.
5. The functions of photo management, Ceph analysis, dental model comparison, etc. help doctors to understand a patient' s situation and progress during treatment.

Clear Aligner System

With PlaniMax software, the tooth arrangement result confirmed by doctor can be calculated into complete treatment plan. CHOICE will manufacture the clear aligner products according to sequential dental models in treatment plans.

Clear aligner

PlaniMax software

Clear aligners are suitable for orthodontic cases such as crowding, spacing, open bite, deep bite, cross bite, relapse and the malocclusion rescue. Thermoplastic material of the aligners is polymer, with the characteristic of biocompatibility, high transparency, high toughness and tear resistance. Patients need to wear a full 22 hours a day and replace a pair of aligner every two weeks to achieve the effect.

Clinical Cases

Minor Adjustment

Anterior crowding case, keep posterior occlusion and do the anterior 3-3 treatment:

- Align anterior 3-3, correct #12 cross-bite
- Midline correction


Before the treatment


After the treatment

Space Closing

The case with lots of spacing and space rearrangement needed:

- Anterior align and spacing close
- need to add attachments during the treatment

Before the treatment

After 10 months

Premolar Extraction

Case of maxillary first pre-molar extraction, with TADs and elastics treatment to avoid tipping caused by space closure:

The time of treatment varies according to the extraction position, the degree of crowding and the way of anchorage.

The accurate time-course prediction needs full evaluation and simulation by PlaniMax software.

Features

- A software as an approved medical device, using 3D animation as a direct bridge with patients.
- Simulates with biomechanics to predict the result.
- Cloud-based storage for treatment photos, Ceph data and study models.
- Combined CT and Ceph to record the changes in occlusion accurately.
- Bite relationship is adjustable to avoid deviation and occlusal interference.
- Offers quantitative analysis, comparison and notification of attachment needs.
- Able to combine clear aligner and conventional treatment.
- Made in Taiwan with class II medical device certification, rapid and flexible manufacturing time.

Processes of Clear Aligner

Initial Consultation

Patients are able to consult via doctors or clinics recommend by CHOICE.

3D Simulation Analysis

Doctors can choose to use traditional cast setup or digital setup for further evaluation.

Plan Confirmation

Doctors give indications of treatment plan to technicians through PlaniMax.

Treatment

Patients should replace their aligner sets according to treatment plan.

Follow- up Appointment

Renew patients' scanned models to do the treatment refinement if necessary.

Data Collection

Patient case data:

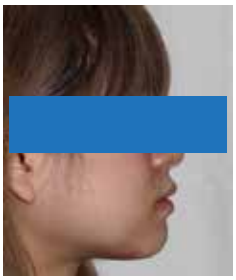
- Scan data/intro-oral scan data (STL)
- Oral/facial photo
- Pano X-ray/ lateral cephalogram

Initial Indication:

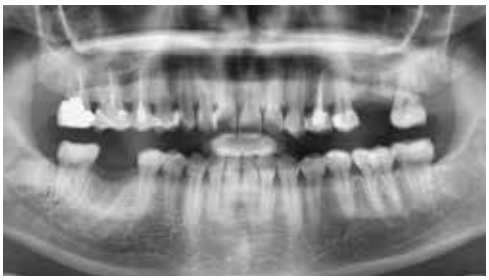
- Tooth extraction (tooth position)
- Molar/ canine relationship (Class I / II / III)
- Attachment / IPR treatment (Y / N)

Facial Front Smile

Facial Profile



Facial Side



Panoramic radiograph

Occlusal Upper

Occlusal Lower

Right

Center

Left

ngemen

lateral cephalogram

Note: Insufficient information

1. Digital/cast models are damaged, or contain bubbles/ holes, and the margin lines / gums cannot be clearly distinguished.
2. Without facial front smile and lateral photo, and lacks of the position of soft tissue midline and occlusal relationship in the indication.
3. Does not provide the current status of root canal, denture or implant.

PlaniMax Orthodontic Planning Software

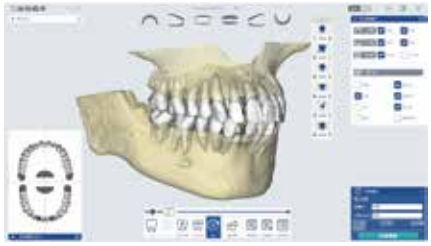
PlaniMax is able to provide clinical analysis and data management required by orthodontists.

1. Management of Medical Records

Doctors are able to manage patient records by their own accounts. Photos and cephalometric analysis records of different dates can be saved in a single case file. Cloud-based storage is a useful aid to cases management and treatment explanations.

2. Cephalometric Analysis and Management

Feature points setup and outlining will be offered based on cephalometric radiographs. The system will then calculate the distance and angles between feature points, which assists in the analysis of jaw relation. The result will ultimately aid doctors in treatment evaluation.

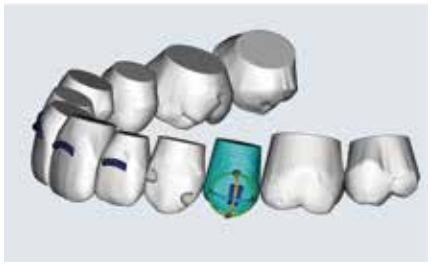


3. Combination with CT digital models

CHOICE serves the combination with CT models, producing root digital model based on the CT scan. PlaniMax can simulate the real movement of root in order to gain root control in the beginning of the treatment.

4. Bite Relationship Adjustment

With the interface of adjustment, the correction of original scanned model bite can be made to avoid interference of incorrect information in the beginning of treatment. Jaw relationship of setup is also adjustable to improve occlusion.



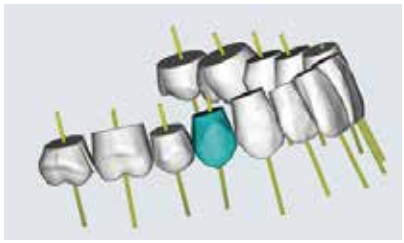
5. Suggestion of Attachment Position

According to the amount of movement and rotation of each tooth, the system will provide suitable attachment for each position.

Software Operating Procedure

1. Dental Casts Upload

Users can upload scanned models of dental casts or related photos for project setup. Users can also upload STL files or send dental casts to CHOICE for digital project setup assistance.



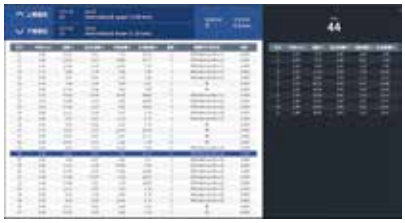
2. Long Axis Definition

Long axis and distal-mesial direction will be defined from view point control, which will then provide to the system for rapid auto tooth segmentation.Margin line adjustment can be used to modify each tooth model.

3. Setup Plan

Multiple choice of tools is user-friendly for doctors to plan and adjust tooth position.

Conventional setup casts from dental lab can also be translated to PlaniMax project.



4. Treatment Time Calculation

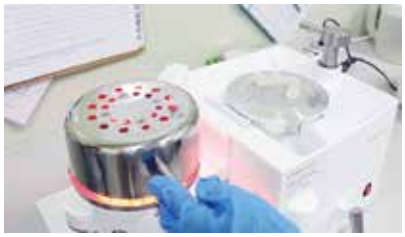
Treatment plan will be confirmed through animation and quantitative data. By setting up maximum movement and amount of rotation in a single stage, the system is able to calculate whole steps of treatment automatically. Doctors can adjust any stage of treatment

5. Confirmation of Plan

PlaniMax is a software as medical device approved by Taiwan FDA. Through 3D animation display of PlaniMax, patients are offered with a clearer understanding of treatment design. Doctors are able to check on data anytime in the cases of attachments or IPR.

6. Project Saving

CHOICE provides a cloud-based storage, allowing users to open projects anywhere and with any device in order to examine setups and results of treatment



7. Manufacture

Accords to the treatment plans confirmed by doctors, CHOICE will manufacture products in our QMS / GMP certified factory.

Comparison of products

	CHOICE BIOTECH	Invisalign	3Shape	Dental lab
Orthodontic records management	Cephalometric radiograph, photo	Occlusal photographs	Occlusal photographs	None
Cloud-based storage of projects	Private account, unlimited capacity	Not provided	Not provided	Not provided
Comparative analysis of treatments	Provided	Not provided	Not provided	Not provided
Setup time requirement	5 days	3 to 4 weeks	Depends	7 days
Web viewer	Provided as approved medical device	Web	Not provided	Not provided
Aligner material	Biocompatible materials	Self-produced (USA)	Choose by 3Shape	Produced by dental lab
Place of manufacture	QMS Factory in Tainan Science Park	Mexico	Depends	Dental lab
Combined with conventional fixed appliances	Able	Unable	Unable	Unable
Time of manufacture	5 days	3 to 4 weeks	Unknown	7 days

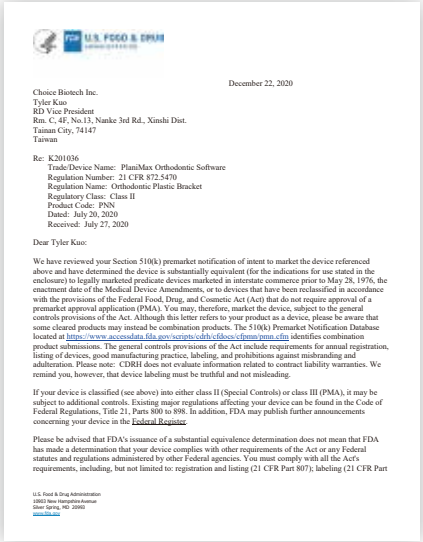
產品認證

ISO 13485:2016

Design and manufacture of dental surgical guide & computer-aided surgical plan software.
Design and manufacture of orthodontic aligner & orthodontic software

Taiwan FDA Class II

“CHOICE”Clear Aligner System



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

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

FDA 510(k) Premarket Notification

CLASS II
“CHOICE” PlaniMax Orthodontic Planning Software

Memo

CHOICE
BIOTECH

The Best Digital Orthodontics Solution Provider

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