April 21, 2020

OrthoSelect, LLC
% Carmine Jabri
President
E.M.M.A International Consulting Group Inc.
27600 Farmington Road, Suite 100
Farmington Hills, Michigan 48334

Re: K192701
Trade/Device Name: DIBS (Digital Indirect Bonding System)
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN, LLZ
Dated: March 20, 2020
Received: March 23, 2020

Dear Carmine Jabri:

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)*
K192701

Device Name
DIBS (Digital Indirect Bonding System)

Indications for Use *(Describe)*
DIBS by OrthoSelect 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 (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 DIBS by OrthoSelect 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.

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

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510(k) Number (K192701)
510(k) SUMMARY – Traditional 510(k)

A summary of information in accordance with requirements of 21 CFR 807.92.

SUBMITTER'S INFORMATION

Sponsor:	OrthoSelect, LLC
Address:	831 E 340 S Suite 170 American Fork, UT 84003, USA
Official Correspondent:	Carmine Jabri E.M.M.A International Consulting Group Inc. +1 248.987.4497 carmine.jabri@emmainternational.com
Date Summary Prepared:	April 20, 2020

DEVICE INFORMATION

Name of Device:	DIBS (Digital Indirect Bonding System)
Common Name:	Orthodontic Software
Classification Name:	21 CFR 872.5470 – Orthodontic plastic bracket
Product Code:	PNN
Secondary Product Code:	LLZ
Device Classification:	Class II

PREDICATE DEVICE

Primary Predicate Device:	K152086 – 3Shape A/S – 3Shape Ortho System

DEVICE DESCRIPTION

DIBS by OrthoSelect is a software system used for the management of 3D scanned orthodontic models of the patients' dentition and allows orthodontic measurements, analysis, inspection, and visualization. The primary purpose of DIBS is to allow virtual planning of orthodontic treatments by simulating tooth movements, virtual placement of orthodontic brackets, and design of orthodontic appliances based on the 3D scanned orthodontic models. Output includes STL files that can be used to make Indirect Bonding Transfer Trays (also called orthodontic bracket placement trays).

The device has no patient contact. DIBS is a software-only device with the following hardware requirements:

Item	Minimum Requirements
OS	Windows 7 or 8 64-bit
RAM	4 GB or more
Monitor Resolution	1280x800 or similar
Video Card Memory	1 GB GeForce
Available HDD Space	250 GB
CPU	IntelCore i3 or higher equivalent
Network	Network Internet Connection
Mouse	With scroll wheel recommended

INDICATIONS FOR USE

DIBS by OrthoSelect 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 (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 DIBS by OrthoSelect 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.

COMPARISON TO PREDICATE DEVICE

DIBS has the same intended uses and is subject to the same regulation as the Ortho System from 3Shape A/S (K152086):

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE
SPONSOR	OrthoSelect	3Shape
TRADE NAME	DIBS	Ortho System
510(k) NUMBER	---	K152086
PRODUCT CODE	PNN	PNN
Secondary Product Code	LLZ	LLZ
INDICATIONS FOR USE	DIBS by OrthoSelect 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 (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	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

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE
SPONSOR	OrthoSelect	3Shape
TRADE NAME	DIBS	Ortho System
510(k) NUMBER	---	K152086
	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 DIBS by OrthoSelect 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.	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.
GENERAL DESCRIPTION	Stand Alone Software	Stand Alone Software
SUPPORTED ANATOMIC AREAS	Maxilla, Mandible	Maxilla, Mandible
PATIENT CONTACT	None	None

Additionally, DIBS has many of the same features that the predicate device, Ortho System from 3Shape A/S (K152086), has:

FEATURE	SUBJECT DEVICE **OrthoSelect DIBS**	PREDICATE DEVICE **3Shape Ortho System**
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
Managing patient and case base data		
Creating, editing, deleting, and copying patient data	Yes	Yes

Creating, editing, deleting, and copying case data	Yes	Yes
Collection of study material	Yes	Yes
Surface scan for intra-oral scanner	Yes	Yes
Surface scan from STL file	Yes	Yes
CT image data	No	DICOM
2D overlay	No	PNG, JPG, BMP
Alignment of study material		
Aligning surface scan and CT image	No	Yes
Aligning cephalometric images	No	Yes
Alignment of 2D overlays (e.g., ideal arch)	Yes	Yes
Ability to check/adjust DICOM visibility	No	Yes
DICOM scan segmentation	No	No
Measuring study material		
2D measurement toolbox	Yes	Yes
3D measurement toolbox	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
Occlusion map	Yes	Yes
Treatment simulation		
2D & 3D simulation	Yes	Yes
Virtual appliance design	Yes	Yes
Orthodontic appliance search	Yes	Yes
Orthodontic appliance virtual preparation	Yes	Yes
Orthodontic appliance design	Yes	Yes
Orthodontic appliance export	Yes	Yes

Differences between the features do not affect the safety or effectiveness of DIBS compared to its predicate device.

PERFORMANCE DATA

Medical device 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 2005). Validation was performed in conformity with IEC 62304 – Medical device software – Software lifecycle processes.

Documentation was also prepared in accordance to FDA guidance documents, “General Principles of Software Validation” (issued January 2002) and “Off-The-Shelf Software Use in Medical Devices” (issued September 1999).

CONCLUSIONS

DIBS has the same intended use as the predicate device, Ortho System (K152086). Both devices are orthodontic software devices regulated under 21 CFR 872.5470 and are intended to aid in orthodontic treatment planning and allow the export of orthodontic appliance designs.

The predicate 3Shape Ortho System (K152086) is additionally regulated as a Radiological Image Processing System under 21 CFR 892.2050 due to its functionality to utilize CT DICOM images as input. DIBS does not have this functionality, however, this difference does not affect the safety or effectiveness of DIBS.

Based on the comparison between indications for use, technological features, performance testing, and software validation testing, DIBS has been shown to be substantially equivalent to the legally marketed device, Ortho System (K152086).