April 2, 2020

Trophy
Marie-Pierre Labat-Camy
Global Regulatory Affairs Senior Manager
4 Rue F. Pelloutier
Croissy-Beaubourg,
Marne La Vallee Cedex 2, 77435 France

Re: K193390
Trade/Device Name: CS Model+
Regulation Number: 21 CFR 872.5470
Regulation Name: Orthodontic Plastic Bracket
Regulatory Class: Class II
Product Code: PNN
Dated: March 4, 2020
Received: March 6, 2020

Dear Marie-Pierre Labat-Camy:

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)*

K193390

Device Name
CS Model+

Indications for Use *(Describe)*

CS Model+ is intended for use as a front-end software tool for management of orthodontic models, detailed analysis, treatment simulation and virtual appliance design options, including dental casts and orthodontic appliances. 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 CS Model+ requires the user to have the necessary training and domain knowledge in the practice of orthodontics.

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

(As per 21 CFR 807.92)

1) **Date 510(k) Summary prepared**

April 2nd, 2020

2) **Contact information**

a) **Submitter information**

Contact: Ms. Marie-Pierre LABAT-CAMY
Phone: +33 (0) 1 64 80 85 26
Address: Trophy
4 Rue F. Pelloutier – Croissy-Beaubourg
77435 Marne La Vallée, Cedex 2
France

b) **United Stated Sales Representative (U.S. Designated Agent)**

Contact: Mr. Sonny T. Nguyen
Phone: +1 (470) 481-4619
Address: Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339

3) **Device Identification**

Trade/Device Name: **CS Model+**
Regulation Number: 21 CFR 872.5470
Common Name: Orthodontic Plastic Brackets
Regulatory Class: II
Product code: PNN

4) **Primary Predicate**

We consider the **CS Model+** to be similar in design, composition and function to the following device, introduced into commercial distribution after May 28, 1976:

Trade/Device Name: Ortho System™
510(k) Number: K171634
510(k) Submitter/holder: 3Shape A/S

Ortho System™ has been found to be substantially equivalent through the 510(k) premarket notification process.

5) Device description

CS Model+ is a software that allows practitioners to apply software imaging tools for management of orthodontic models, detailed analysis, treatment simulation and virtual appliance design. **CS Model+** allows design of virtual models, also known as virtual dental casts. Those can be exported as STL or PLY files which may be used for fabrication of orthodontic models (dental casts). Then, which may be used to fabricate sequential aligner trays or retainers. The production of physical models and the other fabrication processes, such as thermoforming of aligner, is out of scope of Carestream Dental's manufacturing process. Those fabrication processes are done by the user and is under their sole control and responsibility.

It is the responsibility of the user to ensure:

- that all production machines and materials used are suitable for producing models or appliances for orthodontic purposes.
- that all production machines and materials used are FDA cleared.

CS Model+ Indication for Use is the following:

> **CS Model+** is intended for use as a front-end software tool for management of orthodontic models, detailed analysis, treatment simulation and virtual appliance design options, including dental casts and orthodontic appliances. 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 **CS Model+** requires the user to have the necessary training and domain knowledge in the practice of orthodontics.

CS Model+ is intended to be used with the following Carestream Dental's digital imaging devices including:

- Intraoral scanners;
- Extraoral devices with 3D object modality.

CS Model+ allows healthcare professionals to do the following:

- Display digital 2D or 3D views of digital 3D models;
- Adjust the color and opacity of digital 3D models;
- Make indicative measurements of digital 3D models;
- Print and export images of digital 3D models;
- In a digital model, automatically detect the teeth cervical margins, teeth numbering and mesio distal orientations;
- Generate an orthodontic report;
- Create virtual setups;
- Automatically generate virtual setups suitable for aligners treatment;
- Make automatic and customizable export of virtual models;
- Manage the intermediate steps;
- Make refinement during treatment.

6) Indications for Use

CS Model+ is intended for use as a front-end software tool for management of orthodontic models, detailed analysis, treatment simulation and virtual appliance design options, including dental casts and orthodontic appliances. 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 **CS Model+** requires the user to have the necessary training and domain knowledge in the practice of orthodontics.

Comparison of Indications for Use

The indication for use for the **CS Model+** is similar to the primary predicate device Ortho System™ (K171634); the differences do not alter the intended use of the device. Therefore, the **CS Model+** software can be considered substantially equivalent to its predicate device.

7) Substantial Equivalence

a) Summary of the technological characteristics

CS Model+ is a standalone software which has the following PC/laptop hardware requirements:

PC/ Laptop hardware requirements comparison		
Comparison Areas	**CS Model+**	Ortho System™
OS	Windows 10 64-bit	Windows 7, 8 or 10 64-bit
RAM	8 GB	8 GB
Monitor Resolution	1024x768 minimum	1280x800 or similar
Video Card Memory	1 GB	1 GB
Available HDD Space	10 GB	250 GB
CPU	2,4 GHz Intel Duo Core	Intel Core i5 or equivalent
Network	Network Internet connection	Network Internet connection
Mouse	With the wheel button	With the wheel button

CS Model+ has the same intended use and technical characteristics as Ortho System™ (K171634) from 3Shape A/S:

Intended use and technical characteristics comparison		
Comparison Areas	**CS Model+**	Ortho System™
Destination		
Supported anatomic areas	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
Supported PC formats		
Operating System	Windows	Windows
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 / Acquisition Data Formats Support		
Standalone software module	Yes	Yes
Surface scan from intra-oral scanner	Yes	Yes
Image data	DICOM, PNG, JPG, STL	DICOM, PNG, JPG, STL
Alignment of study material		
Alignment of 2D overlays (e.g. ideal arch)	Yes	Yes
Measuring study material		
2D measurement toolbox	Yes	Yes
3D measurement toolbox	Yes	Yes
Analyzing study material		
Arch shape	Yes	Yes
Tooth width	Yes	Yes
Bolton	Yes	Yes
Space analysis	Yes	Yes
Overjet/overbite	Yes	Yes
Occlusion map	Yes	Yes
Treatment simulation		
3D simulation	Yes	Yes
Virtual appliance design		
Orthodontic appliance virtual preparation	Yes	Yes
Orthodontic appliance design	Yes	Yes
Orthodontic appliance export	Yes	Yes

b) Nonclinical testing

Prior to release, software verification and validation testing of the **CS Model+** have been performed in accordance with the FDA Guidance Document "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices" (Issued on May 11, 2005). Testing confirmed that **CS Model+** is stable and operating as designed.

The risk management procedures have been applied to the development of the software and the risks identified have been mitigated and reduced to acceptable levels.

All test results have been reviewed and approved, showing the **CS Model+** software to be substantially equivalent to the primary predicate Ortho System™ (K171634).

c) Clinical testing

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

8) Conclusion

Based on a comparison of intended use, indications, principle of operations, features and technical data, and the test results, **CS Model+** is found to be substantially equivalent to the primary predicate Ortho System™ (K171634).