Trophy
% Ms. Marie-Pierre Labat-Camy
Global Regulatory Affairs Senior Manager
4 Rue F. Pelloutier – Croissy-Beaubourg
77435 Marne La Vallée, Cedex 2
FRANCE

March 13, 2020

Re: K200183
Trade/Device Name: CS 9600
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: Class II
Product Code: OAS
Dated: January 22, 2020
Received: January 24, 2020

Dear Ms. 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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

ATTACHMENT 7

INDICATIONS FOR USE STATEMENT

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)*

K200183

Device Name

CS 9600

Indications for Use *(Describe)*

The CS 9600 is extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The CS 9600 can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

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

K200183

1. Date 510(k) Summary prepared

March 11, 2020

2. Submitter information

Applicant
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France
Phone: +33 1 64 80 85 26
Contact person: Ms. Marie-Pierre LABAT-CAMY

United Stated Sales Representative (U.S. Designated Agent):
Carestream Dental LLC
3625 Cumberland Boulevard, Suite 700,
Atlanta, GA USA 30339
Phone: +1 (470) 481-4619
Contact: Mr. Sonny T. Nguyen

3. Device name and classification

Trade name: **CS 9600**
Regulation number: 21 CFR 892.1750
Regulation name (classification name): Computed tomography x-ray system
Common name: Cone-beam computed tomography system
Device Class: II
Product Code: OAS

4. Predicate device and reference device

We consider the **CS 9600** to be similar in design, composition and function to the following primary predicate device and reference device introduced into commercial distribution after May 28, 1976:

Primary Predicate Device Name	510(k)	Company Name
CS 9600	K181136	Trophy

Regulation number: 21 CFR 892.1750
Regulation name (classification name): Computed tomography x-ray system
Common name: Cone-beam computed tomography system
Device Class: II
Product Code: OAS

Reference Device Name	510(k)	Company Name
CS 8100SC	K151087	Trophy

Regulation number: 21 CFR 872.1800
Regulation name (classification name): Extraoral source x-ray system
Common name: X-ray imaging device
Device Class: II
Product Code: MUH

5. Device Description

CS 9600 is an extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxilofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The **CS 9600** can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

CS 9600 is a cone-beam computed tomography (CBCT) x-ray system. It means **CS 9600** rotates around the patient, capturing data using a cone-shaped x-ray beam. These data are used to reconstruct a two or a three-dimensional (3D) image of the following regions of the patient's anatomy: dental (teeth); oral and maxillofacial region (mouth, jaw and neck); ears, nose and throat region (ENT); cervical spine or wrist region.

Additional features such as low dose mode, scout image and metal artifact reduction are also provided by the **CS 9600.**

The **CS 9600** can also be upgraded with cephalometric modality. The cephalometric modality of the proposed device **CS 9600** is the same than the one available in the reference device K151087. The cephalometric mode works with a narrow beam linear scanning process called a "slot technique". The patient head is scanned in lines with a flat, fan-shaped x-ray beam.

6. Indication for use

CS 9600 is an extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxilofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.

The **CS 9600** can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

7. Substantial Equivalence

The subject device **CS 9600**, the primary predicate device K181136 and the reference device K151087 have the same intended use: extraoral x-ray systems that are intended to produce digital X-ray images at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.
Both the **CS 9600** and primary predicate device are intended as Cone-Beam Computed Tomography. The primary predicate device K181136 has the most similar indication for use and technological characteristics with the proposed device **CS 9600.**

Traditional 510(k) Submission for CS 9600

The table below provides the summary of the technological characteristics of **CS 9600** compared to the primary predicate device.

	Proposed device	**Primary Predicate Device**
COMPANY NAME **MODEL NAME**	**Trophy** **CS 9600**	**Trophy** **CS 9600**
510(K) Number		**K181136**
Indication for use	**CS 9600** is an extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients. The **CS 9600** can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.	CS 9600 is an extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.
Performance specification	• Panoramic modality • 3D modality • Cephalometric modality (optional)	• Panoramic modality • 3D modality
Rated line voltage	100-240 Vac - 50/60 Hz	Same
X-ray tube voltage	60-90 kV 60-120 kV (in option)	Same
X-ray tube current	2-15 mA	Same
X-ray tube	DF-071G or OX/120-0307	Same
Tube focal spot	0.3 or 0.7 mm	Same
Patient sizes	4 patients sizes: child, small adult, medium adult, large adult	Same

The proposed **CS 9600** and the primary predicate device CS 9600 (K181136) have the same panoramic two-dimensional modality and three-dimensional 3D modality.

COMPANY NAME **MODEL NAME**	**Proposed device** **Trophy** **CS 9600**	**Primary Predicate device** **Trophy** **CS 9600**
510(K) Number		**K181136**
Two-dimensional modality: PANORAMIC		
Sensor technology	CMOS	Same
Image field	6.4 x 140 mm (for adult patient size) 6.4 x 120 mm (for child patient size) 120 x 140 mm (for sinus one-shot exam)	Same
Gray scale	16384 – 14 bits	Same
Magnification	1.28	Same
Radiological Exams	• Full panoramic • Segmented panoramic • Bitewing • Maxillary sinus • Lateral TMJ x2 and Lateral TMJx4 • Sinus AP / PA / Lateral • Orthogonal panoramic	Same
Exposure time	0.5 to 13 seconds	Same

COMPANY NAME MODEL NAME	Proposed device Trophy CS 9600	Primary Predicate device Trophy CS 9600
510(K) Number		K181136
Three-dimensional modality: 3D		
Sensor technology	CMOS	Same
Field of View (cm) diameter x height	• 4 x 4 • 5 x 5 (child 4 x 4) • 5 x 8 • 6 x 6 • 8 x 5 • 8 x 8 • 10 x 5 (child 8 x 5) • 10 x 10* (child 8 x 8) • 12 x 5 • 12 x 10* • 16 x 6 • 16 x 10* • 16 x 12* • 16 x 17* **with tip of the volume*	Same
Radiological Exams	• Tooth/Teeth • Jaw (full, upper or lower) • Upper cervical spine • TMJ • Face • ENT • Wrist	Same
Gray scale	16384 – 14 bits	Same
Magnification	1.4	Same
Voxel size (µm)	75, 150, 300 and 400	Same
Exposure time	3-20 seconds	Same
OTHER INFORMATION		
Low dose mode	Yes	Same
Scout image	Yes	Same
3D Face Photo	Yes in option (CS Face Scan)	Same
Metal Artefact Reduction	Yes in option (CS MAR)	Same
Concerned anatomical sites	• Dento-maxillofacial area • ENT area • Cervical spine • Hand/wrist	Same
Sensor model	CGF81	Same
Sensor active area (mm)	120 x 140	Same
Pixel size (µm)	100 x 100	Same
Sensor resolution	1200 x 1400 pixels	Same
Limiting resolution	5 lp/mm	Same
MTF, X-ray (%) at 1 lp/mm, Typical	60	Same
DQE, X-ray (%) at 0 lp/mm, Typical	60	Same

The proposed **CS 9600** and the primary predicate device CS 9600 (K181136) have the same panoramic two-dimensional modality and three-dimensional 3D modality.
The main difference between the proposed **CS 9600** and the primary predicate device K181136 is the difference in 2D imaging capabilities available with the addition in the proposed **CS 9600** of the optional two-dimensional cephalometric modality.
The proposed device **CS 9600** can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

Traditional 510(k) Submission for CS 9600

When the **CS 9600** is upgraded with cephalometric modality to produce cephalometric digital X-ray images, the cephalometric modality available is the same as the cephalometric modality available in previously cleared reference device K151087.

The following table provides the summary of the technological characteristics of the cephalometric modality of **CS 9600** compared to the reference device K151087.

	Proposed device	**Reference Device**
COMPANY NAME **MODEL NAME**	**Trophy** **CS 9600**	**Trophy** **CS 8100SC**
510(K) Number		**K151087**
Indication for use	**CS 9600** is an extraoral system intended to produce two-dimensional and three-dimensional digital X-ray images of the dento-maxillofacial, ENT (Ear, Nose and Throat), cervical spine and wrist regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients. The **CS 9600** can be upgraded to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.	The CS 8100SC and the CS 8100SC Access are indicated to produce complete and segmented tomographic digital panoramic and **cephalometric digital X-ray images** to be used at the direction of healthcare professionals of the dento-maxillofacial region of the human anatomy as diagnostic support for pediatric and adult patients. **This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.** In addition, the CS 8100SC is provided with the panoramic radiological exam option which allows the display of one determined segment of the dental structures using the capability of the system to explore each slide during an exam.
Two-dimensional modality: CEPHALOMETRIC		
Sensor technology	CMOS	CMOS
Radiological Exams	• Lateral • Frontal AP or PA • Oblique • Submento-vertex • Carpus (optional)	Same
Field of View (cm) LxH	18x18, 18x24 and 26x24	Same
Gray scale	16384 – 14 bits	Same
Exposure time	2.96 to 10 seconds	3 to 10 seconds
Sensor model	CGC95	Same
Sensor active area (mm)	131.6 x 6.4	Same
Pixel size (µm)	100 x 100	Same
Sensor resolution	1316 x 64 pixels	Same
Limiting resolution	5 lp/mm	Same
MTF, X-ray (%) at 1 lp/mm, Typical	60	Same
DQE, X-ray (%) at 0 lp/mm, Typical	60	Same

When the **CS 9600** is upgraded with cephalometric modality to produce cephalometric digital X-ray images, the proposed **CS 9600** and the reference device K151087 have the same cephalometric modality. Both systems are able to produce cephalometric digital X-ray images. This includes imaging the hand and wrist to obtain carpus image for growth and maturity assessment.

While the indication for use of primary predicate device K181136 and reference device K151087 are different, both devices have the same intended use, namely extraoral x-ray system.
The proposed device **CS 9600** combines the indication for use of both the primary predicate device K181136 with the part of indication for use related to the cephalometric modality of the reference device K151087.

8. Non-Clinical Performance Data

The Testing to verify the performance requirements of the subject device **CS 9600** was conducted and including in this premarket notification.

Standards Conformance:
EMC and Electrical Safety testing were performed respectively by LCIE and UL laboratory and found to meet all the requirements in standards IEC 60601-1: 2005 with A1 2012 (AAMI/ANSI ES60601-1:2005/R(2012), IEC 60601-1-2: 2014, IEC 60601-1-3: 2008 with A1 2013, IEC 60601-2-63: 2017 and IEC 62304: 2006 with A1 2015.

CS 9600 meets the provisions of NEMA PS 3.1-3.20, Digital Imaging and Communications in Medicine (DICOM) Set. The software contained in **CS 9600** has been validated according to FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices and FDA Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

The **CS 9600** provides design features and instructions for pediatric population according to the FDA Guidance on Pediatric Information for X-ray Imaging Device Premarket Notifications.

Performance Testing:
Since there is no change on the two-dimensional panoramic and three-dimensional 3D modalities of the proposed device **CS 9600** compared to the primary predicate device K181136, the performance testing was conducted on the new cephalometric modality added in the proposed device **CS 9600.** Following the FDA Guidance for the Submission of 510(k)'s for Solid State X-ray imaging Devices, for the new cephalometric imaging applications, clinical images representative of the range of the different cephalometric radiological exams were taken. The cephalometric images were reviewed by a qualified expert and were evaluated to be of acceptable clinical effectiveness for the proposed indications for use. The **CS 9600** set of images were deemed to be of a clinically usable diagnostic quality.

Non clinical and bench testing was conducted as part of design control to ensure the substantial equivalence of **CS 9600** with the primary predicate device K181136 and reference device K151087. **CS 9600** has been tested to ensure that the system as a whole operated in a safe and effective manner that is substantially equivalent to the primary predicate device and for the cephalometric modality to the predicate device. The results of the performance testing support substantial equivalence.

9. Conclusion

The comparison of characteristics supports substantial equivalence. **CS 9600** is as safe and effective as the primary predicate device K181136 and as the reference device K151087 for the cephalometric modality.

CS 9600 is considered substantially equivalent to the primary predicate device K181136 because both have the most similar indication for use and technological characteristics. Both have the same panoramic two-dimensional modality and three-dimensional 3D modality. Cephalometric modality added in the proposed device **CS 9600** is identical to the cephalometric modality included in previously cleared reference device K151087. The compared technical features for cephalometric imaging technology, Field of View, and other basic characteristics are matching very closely. There is no difference in the new cephalometric modality available in the proposed device **CS 9600** and the cephalometric modality available on the reference device K151087. Therefore, the addition of the cephalometric modality to the **CS 9600** does not raise questions of safety and effectiveness and does not have any effect on performance in practice.