May 24, 2018

Trophy
% Marie-Pierre Labat-Camy
Global Regulatory Affairs Senior Manager
4 Rue F. Pelloutier - Croissy Beaubourg
77435 Marne la Vallee Cedex 2
FRANCE

Re: K181136
Trade/Device Name: CS 9600
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: OAS
Dated: April 27, 2018
Received: April 30, 2018

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs, Ph.D.
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
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)*

K181136

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.

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.

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510K SUMMARY

Date 510(k) Summary prepared:
May 16, 2018

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

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

Trade/Device Name: Planmeca ProMax 3D Max, Planmeca Maximity
510(k) Number: K160506
Date of clearance: May 20, 2016
Regulation number: 892.1750
Regulation name (classification name): Computed tomography x-ray system
Common name: Cone-beam computed tomography system
Device Class: II
Product Code: OAS

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.

CS 9600 is 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, metal artifact reduction are also provided by the **CS 9600.**

Intended 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.

Substantial Equivalence:

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

COMPANY NAME **MODEL NAME**	**Trophy** **CS 9600**	**Planmeca Oy** **Planmeca ProMax 3D Max, Planmeca Maximity**
510(K) Number		**K160506**
Indication for use	The **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 **Planmeca ProMax 3D Max** or **Maximity** is a system intended to produce two-dimensional (2D) and three-dimensional (3D) digital X-ray images of the dento-maxillofacial, cervical spine and ENT (Ear, Nose and Throat) regions at the direction of healthcare professionals as diagnostic support for pediatric and adult patients.
GENERAL SPECIFICATIONS		
Performance specification	• Panoramic modality • 3D modality	• Panoramic modality • 3D modality
Rated line voltage	100-240 Vac - 50/60 Hz	100-240 Vac – 50/60 Hz
X-ray tube voltage	60-90 kV 60-120 kV (in option)	60-96 kV 60-120 kV (in option)
X-ray tube current	2-15 mA	1-14 mA
X-ray tube	Toshiba DF-071G or CEI OX/120-0307	Toshiba D-067SB or Toshiba D-059SBR or SXR 130-10-0.5 SC
Tube focal spot	0.3 or 0.7 mm	0.5 or 0.6 mm
Patient sizes	4 patients sizes: child, small adult, medium adult, large adult	5 patients sizes: child, small adult, medium adult, large adult, extra large adult
Sensor technology	CMOS	Amorphous silicon
Sensor model	CGF81	2520D
Sensor active area (mm)	120 x 140	193 x 242
Pixel size (µm)	100 x 100	127 x 127
Sensor resolution	1200 x 1400 pixels	1536 x 1920 pixels

Gray scale	16384 – 14 bits	32768 – 15 bits
Limiting resolution	5 lp/mm	3.94 lp/mm
MTF, X-ray (%) at 1 lp/mm, Typical	60	≥48
DQE, X-ray (%) at 0 lp/mm, Typical	60	70
Unit dimensions (mm)	1284 (L) x 1669 (D) x 2526 (H)	1280(L) x 1430 (D) x 2390 (H)
Two-dimensional modality: PANORAMIC		
Radiological Exams	• Full panoramic • Segmented panoramic • Bitewing • Maxillary sinus • Lateral TMJ x2 and Lateral TMJx4 • Sinus AP / PA / Lateral • Orthogonal panoramic	• Standard panoramic • Horizontal and vertical segmenting panoramic • Bitewing • PA linear sinus • Lateral TMJ (closed & open) • Sinus: AP / PA / Lateral • Orthogonal panoramic
Magnification	1.28	1.2
Exposure time	2-14 seconds	2.7-16 seconds
Dose Estimation for Full Panoramic (DAP) (mGy.cm²)	• Child: 68 kV - 6.3 mA – 10.9 s = 58.5 • Adult Small: 72 kV – 6.3 mA – 11.6 s = 87.8 • Adult Medium: 73 kV – 8 mA – 12.3 s = 122 • Adult Large: 76 kV – 8 mA – 13 s = 139	• Child: 72 kV - 16 mA - 8.6 s = 55 • Adult Small: 76 kV - 16 mA - 9.9 s = 92 • Adult Medium: 80 kV - 16 mA - 9.9 s = 111 • Adult Large: 84 kV - 16 mA - 10.2 s = 136
Three-dimensional modality: 3D		
Radiological Exams	• Tooth/Teeth • Jaw (full, upper or lower) • TMJ • Face • ENT • Upper cervical spine • Wrist	• Tooth/Teeth • Jaw (full, upper or lower) • Temporal bone • Face • Skull • ENT • Vertebrae
Magnification	1.4	1.4
Voxel size (µm)	75, 150, 300 and 400	75, 100, 150, 200, 400 and 600
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*	5 x 5 (child 4.2 x 5) 10 x 5.5 (child 8.5 x 5) 10 x 9 (child 8.5 x 7.5) 10 x 13 (child 8.5 x 11) 13 x 5.5 (child 11 x 5) 13 x 9 (child 11 x 7.5) 13 x 10 13 x 13 (child 11 x 11) 13 x 16 (child 11 x 13.6) 23 x 6 23 x 10 23 x 16 (max without stitching) 23 x 26 (max with vertical stitching = two vertical image volumes)
Exposure time	3-20 seconds	2.8-18 seconds
Dose Estimation for Field of View 5 x 5 cm (mGy.cm²)	• Child: 80 kV – 2.5 mA – 15 s = 211 • Adult Small: 90 kV – 2 mA – 15 s = 220 • Adult Medium: 90 kV – 4 mA – 15 s = 440 • Adult Large: 90 kV – 5 mA – 15 s = 550	• Child: 96 kV – 4.5 mA – 12 s = 288 • Adult Small: 96 kV – 5.6 mA – 12 s = 472 • Adult Medium: 96 kV – 7.1 mA – 12 s = 598 • Adult Large: 96 kV – 9 mA – 12 s = 758

OTHER INFORMATION		
Low dose mode	Yes	Yes
Scout image	Yes	Yes
3D Face Photo	Yes in option (CS Face Scan)	Yes in option (Planmeca ProFace)
Metal Artefact Reduction	Yes in option (CS MAR)	Yes in option (Planmeca ARA)
Concerned anatomical sites	• Dento-maxillofacial area • ENT area • Cervical spine • Hand/wrist	• Dento-maxillofacial area • ENT area • Cervical spine • Hand/wrist (with cephalostat module available as an option)

Two-dimensional and three-dimensional modalities, performances and imaging applications of the **CS 9600** are similar to those of primary predicate device K160506.
CS 9600 and the predicate device K160506 share:

- equivalent general technological characteristics in terms of X-ray tube voltage, X-ray tube current, tube focal spot or patient sizes;
- similar key imaging characteristics of the digital sensor;
- same two-dimensional panoramic and three-dimensional radiological programs;
- equivalent dose values on each modality.

In addition, both **CS 9600** and the predicate device K160506 provides the same additional features such as:

- Low dose mode to capture image with a minimal dose of radiation.
- Scout image to capture 2D views to verify correct positioning to avoid risk of retake.
- 3D Face Photo to capture 3D facial picture to visualize soft tissue.
- Metal Artifact Reduction to remove shadows and streaks caused by metal restorations and root fillings.

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: 2012 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.

Performance Testing:

The performance testing for imaging applications was carried out taking clinical images representative of the range of the different radiological exams available. The 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 predicate device. The substantial equivalence for the proposed indication for use is substantiated through verification and validation testing of **CS 9600** as a cone-beam computed tomography x-ray system that is capable of providing digital 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. **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.

Conclusion:

The comparison of characteristics supports substantial equivalence. **CS 9600** is as safe and effective as the predicate device K160506.

CS 9600 is considered substantially equivalent to the predicate device K160506 because the intended use of the subject device **CS 9600** and the predicate device is identical. The compared technical features for imaging technology, Field of View, imaging parameters, resolution, and other basic characteristics are matching very closely. The differences are so small that they do not raise questions of safety and effectiveness and they do not have any effect on performance in practice.