510(k) Summary
CS 7600

SEP 2 3 2011

1. Company Identification

Carestream Health, Inc.
150 Verona Street
Rochester, NY 14608
Establishment Registration: 1315356

2. Contact Person

Daniel Hoefer
Manager, Regulatory Affairs, Carestream Dental
1765 The Exchange
Atlanta, GA 30339
Tel 770 226 3287
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3. Device Name

Commercial name:	*CS 7600*
Common name:	Dental Computed Radiography System
Classification name:	Extraoral source x-ray system

4. Device Classification

Class: II, 21 CFR 872.1800
Product Code: MUH

5. Intended Use

The CS 7600 is a digital intraoral dental radiographic imaging system intended for use by dentists and dental sub-specialists. The system captures, digitizes, displays and stores diagnostic intraoral radiographic images. It consists of a scanner, re-usable imaging plates, acquisition software, disposable hygienic barrier envelopes, and optional Scan & Go device.

6. Device Description

The CS 7600 is a computed radiography system for dental intraoral applications. Imaging plates (i.e., storage phosphor plates) are exposed in the same way as traditional x-ray film. The x-ray images on these plates are then fed into a small computed radiography system and scanned using a laser. The scanned image data from the plates is digitized, and the images are displayed on a monitor and saved to computer.

The CS 7600 system is capable of scanning the X-ray exposed imaging plates at various speeds, sizes and resolutions. Once an imaging plate is scanned, the image data is automatically erased from the plate and the plate ejected for reuse.

Re-usable intraoral imaging plates of sizes 0, 1, 2, 3 and 4 are included with the device, as are disposable hygienic barrier sheaths. The system includes an optional Scan and Go system, which uses RFID technology to automatically recognize imaging plates as they are scanned.

7. Substantial Equivalence

The CS 7600 is substantially equivalent the Kodak CR 7400 (K060079) and the Soredex Digora Optime (K041050). Each listed device is a computed radiography device utilizing phosphor plates for dental diagnostic imaging. The devices are equivalent in terms of indications for use, operating principle and technology, energy used, and materials.

8. Non-Clinical testing

Verification and validation testing of the CS 7600 was performed on software, hardware systems, media, and on the complete assembled device. The RFID technology has been tested for compliance with FCC and international rules for low power transmitters.

Results of testing demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

9. Conclusion

The CS 7600 is substantially equivalent to the predicate devices listed above. Testing has demonstrated that it is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Mr. Daniel Hoefer
Manager, Regulatory Affairs
Carestream Health, Inc.
1765 The Exchange, Inc.
ATLANTA GA 30339

SEP 23 2011

Re: K111649
Trade/Device Name: CS 7600
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: September 8, 2011
Received: September 9, 2011

Dear Mr. Hoefer:

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.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

The CS 7600 is indicated for use in dental digital radiography using imaging plates (phosphor storage screens) for dental intra-oral x-ray imaging.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The-Counter
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K111649