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**510(k) Summary
CS 1600 Intraoral Camera**

1. Company Identification

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

2. Contact Person

Daniel Hoefler
Manager, Regulatory Affairs, Carestream Dental
1765 The Exchange
Atlanta, GA 30339
Tel 770 226 3287
Fax 770 850 5011

3. Device Name

Commercial name: *CS 1600 Intraoral Camera*
Common name: Intraoral Camera with Fluorescence Caries Detection
Classification name: Laser Fluorescence Caries Detection Device

4. Device Classification

Class: II
Product Code: NBL

5. Intended Use

The CS 1600 Intraoral Camera (CS 1600) is intended for chairside use by health professionals during oral health examinations. It provides magnified digital color images of intraoral or extraoral anatomy via a video monitor or Personal Computer (PC). Both still and video images can be captured and stored.

In Caries Detection mode, the CS 1600 is intended as an aid in the detection and diagnosis of dental caries. It provides both video mode and still image detection mode. In still image mode, it provides a color-coded indication of the degree of fluorescence loss for affected areas of the tooth.

The digital video and still images may be digitally recorded for use with computerized patient records.

6. Device Description

The CS 1600 Intraoral Camera (CS 1600) is an intraoral camera system that also includes an optical caries detection system based on fluorescence imaging with reflectance

enhancement. The system is intended for use by healthcare professionals in dental and dental sub-specialty clinical settings.

The system consists of an intraoral camera assembly which is connected via USB connection to a PC, and associated image acquisition software and accessories. Accessories include hygienic barrier sheaths and a collar attachment for the camera assembly that is used for maintaining an optimal working distance in either caries detection mode.

7. Substantial Equivalence

The CS 1600 is substantially equivalent the Kodak 1500 Intraoral Camera (Carestream Health, Inc., K091186), to the Inspektor Pro (Inspektor Dental Care bv, K040063) and to the SoproLife (K092583, Sopro).

- The Kodak 1500, SoproLife, and CS 1600 are each intended for use in dental or dental sub-specialty intraoral video image acquisition, for the purposes of viewing the oral cavity and patient communication.
- The CS 1600, Inspektor Pro, and SoproLife are each intended for use as an aid in the detection and/or diagnosis of dental caries. The principle of operation for each fluorescence caries detection device is substantially equivalent.
- The technological characteristics are equivalent. Each device consists of a digital video camera with 0.25 inch CCD sensor assembled within a camera hand piece. Each connects either to a docking station or directly to a computer via USB, and displays on a chairside monitor. Video formats are similar.
- The intended users of each device are the same or equivalent. Each is intended for use by dentists and other oral health specialists.
- All of the devices are substantially equivalent in terms of energy used or delivered, labeling, materials, biocompatibility, workflow, and technology.
- All of the devices conform to equivalent international standards for safety of medical devices.

8. Non-Clinical testing

Bench top performance testing of the CS 1600 was performed on Hardware sub-systems, Software sub-systems, and on the complete assembled device. The system also has undergone laboratory testing for mechanical, electrical, biocompatibility and EMC/EMI compliance with standards.

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

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9. Clinical Testing

Clinical testing of the system in each caries detection mode has been completed. The conclusion of the study verified the efficacy for the intended use of the device under clinical conditions.

10. Conclusion

The CS 1600 Intraoral Camera is substantially equivalent to the predicate devices listed above. Testing has demonstrated that it is safe and effective for its intended use.



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

Carestream Health, Inc.
C/O Mr. Daniel Hoefler
Manager, Regulatory Affairs, Carestream Dental
Carestream Dental, LLC
1765 The Exchange
Atlanta, Georgia 30339

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Re: K111423
Trade/Device Name: CS 1600 Intraoral Camera
Regulation Number: 21 CFR 872.1745
Regulation Name: Laser Fluorescence Caries Detection Device
Regulatory Class: II
Product Code: NBL
Dated: February 23, 2012
Received: February 24, 2012

Dear Mr. Hoefler:

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.

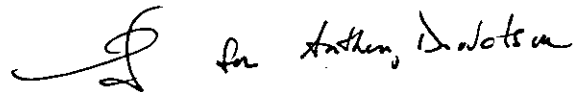
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson". The signature is stylized and written in cursive.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital;
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

The CS 1600 is indicated for use by health professionals as an aid in the detection of dental caries.

It is also indicated for use in viewing and capturing intraoral or extraoral color video images for the purpose of:

- Allowing practitioners to view and magnify all regions of the oral cavity
- Assisting in communication with the patient by providing a view of treatment areas before and after a procedure
- Providing images for documentation in patient records.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter

Susan Ruess

(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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