510(k) Summary
CS Orthodontic Imaging and CS OMS Imaging software

1. Company Identification
   Carestream Dental LLC
   1765 The Exchange
   Atlanta, GA 30339
   Establishment Registration 1226003
   Owner/Operator: Carestream Health, Inc.
   Owner/Operator Registration: 9097221

2. Contact Person
   Daniel Hoefer
   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 Orthodontic Imaging, CS OMS Imaging
   Common name: Dental Imaging Software
   Classification name: System, Image Processing, Radiological

4. Device Classification
   Class: I, 21 CFR 892.2050
   Product Code: LLZ

5. Intended Use
   CS Orthodontic Imaging and CS OMS Imaging software is intended for use by
   orthodontists, oral surgeons, and their clinical staffs in storing and organizing images,
   including digital photographs, x-rays, and others. The system includes the capability to
   trace a cephalometric x-ray, analyze the measurements taken, and make growth or
   surgical predictions.

6. Device Description
   CS Orthodontic Imaging and CS OMS Imaging software is a modification of currently
   legally marketed Kodak Orthodontic and OMS Imaging v8.0 software (K043104). The
   software is intended for installation at orthodontic or oral surgery clinics and offices on
   general purpose off-the-shelf computers systems (PCs) running Microsoft Windows in a
   peer-to-peer network.
Both the modified and unmodified devices consist of imaging software for orthodontic and oral surgery practices. The software provides the ability to connect satellite offices and may be marketed as a base system, with additional modules offered as options. The base system includes the storage, annotation and display of images. The optional Analysis module enables the user to trace the cephalometric x-rays using standard analyses. The optional Planner module enables the user to simulate orthodontic or surgical treatment in order to communicate treatment objectives or demonstrate and explain potential surgery to the patient.

When used with Carestream’s panoramic, cephalometric, and other imaging systems, the device provides an interface that enables the practitioner to acquire radiographic images of the dentomaxillofacial region. The software then allows the user to visualize anatomical structures through the use of a computer display and store the information electronically in a clinical software program. CS Orthodontic and OMS Imaging software includes records of hard and softcopy charts, treatment plans, clinical notes, and clinical exam data. The software also enables the user to retrieve an electronic copy of an x-ray image from other imaging systems.

The device includes options for image viewing or presentation, including thumbnail viewing, single image viewing, and merging images into a letter (i.e., as part of a written communication to the patient). The image manipulation options include grayscale, invert, emboss, brightness, contrast, gamma, sharpen, median, d-speckle, hue, saturation, equalize, flip, mirror, masking, and rotate functions. Image annotation functions allow the user to add text to images, to measure distances and angles, magnify images, and other functions.

CS Orthodontic and OMS Imaging software can be integrated with Carestream’s dental and dental sub-specialty practice management system software or used as a stand-alone product.

7. **Substantial Equivalence**

CS Orthodontic Imaging software and CS OMS Imaging software is substantially equivalent to Kodak Orthodontic and OMS Imaging 8.0 (K043104). See comparison table below (pages 3-4).

8. **Non-Clinical testing**

Verification and validation testing of the CS Orthodontic Imaging and CS OMS Imaging software has been performed, including verification of all specified software and hardware interfaces. Results of testing demonstrate that the device is safe and effective in meeting user requirements in accordance with its intended use.

9. **Conclusion**

CS Orthodontic Imaging and CS OMS Imaging software is substantially equivalent to Kodak Orthodontic and OMS Imaging 8.0, the predicate device listed above.
# Comparison Table

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Kodak Orthodontic and OMS Imaging 8.0</th>
<th>CS Orthodontic and OMS Imaging v11.0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k) number</strong></td>
<td>K043104</td>
<td>pending</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>PracticeWorks Systems, LLC</td>
<td>Carestream Dental LLC (formerly PracticeWorks Systems, LLC)</td>
</tr>
<tr>
<td>Branding</td>
<td>Kodak</td>
<td>CS</td>
</tr>
<tr>
<td>Indications for use</td>
<td>Indicated for Use by Orthodontists and clinical staff for storing and organizing digital images, including digital photographs and x-rays. The device includes the capability to trace digital cephalometric radiographs, analyze measurements taken, and make growth projections</td>
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</tr>
<tr>
<td>Platform</td>
<td>IBM-compatible PC or PC network</td>
<td>Same</td>
</tr>
<tr>
<td>Operating System</td>
<td>Microsoft Windows</td>
<td>Same</td>
</tr>
<tr>
<td>User Interface</td>
<td>Mouse, Keyboard</td>
<td>Mouse, Keyboard</td>
</tr>
<tr>
<td>Image Input Sources</td>
<td>Images can be scanned, loaded from scanners, digital cameras or card readers, or imported from a radiographic imaging device.</td>
<td>Images can be scanned, loaded from digital cameras or card readers, or imported from a radiographic imaging device.</td>
</tr>
<tr>
<td>32-bit software</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Image formats</td>
<td>Multiple, including DICOM</td>
<td>Multiple, including DICOM</td>
</tr>
<tr>
<td>Patient Database Compatibility</td>
<td>Access</td>
<td>SQL</td>
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<tr>
<td>User Functions</td>
<td></td>
<td></td>
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<tr>
<td><strong>Include Image measurement tools</strong></td>
<td>Yes (linear distance, angle)</td>
<td>Yes (linear distance, angle)</td>
</tr>
<tr>
<td>Interface with Carestream imaging devices</td>
<td>Image acquisition from:  - Kodak 8000 panoramic imaging system, Kodak 8000c pan/ceph,  - RVG 5000 intraoral sensor,  - Kodak 1000 Intraoral camera</td>
<td>Image acquisition from:  - Kodak 8000 panoramic imaging system, Kodak 8000c pan/ceph,  - Kodak 9000/9000C/9000 3D  - Kodak 9500 3d Imaging system,  - CS 9300/9300c 3d imaging system  - RVG 6000, RVG 5000, RVG 6100, RVG 5100, and RVG 6500 intraoral sensors  - Kodak 1000, Kodak 1500  - CR 7400 Dental computed</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Feature</th>
<th>Carestream Dental, LLC radiography systems</th>
</tr>
</thead>
<tbody>
<tr>
<td>Image viewing</td>
<td>Full, side-by-side, gallery, thumbnail</td>
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<tr>
<td>Image manipulation</td>
<td>Full, side-by-side, gallery, thumbnail, filmstrip</td>
</tr>
<tr>
<td>Cephalometric Tracing</td>
<td>In addition to user-configured analysis, standard orthodontic tracing analyses include:</td>
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<tr>
<td></td>
<td>- Downs</td>
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<td></td>
<td>- Jarabek</td>
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<td></td>
<td>- McNamara</td>
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<td></td>
<td>- Ricketts</td>
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<td></td>
<td>- Roth</td>
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<td></td>
<td>- Sassouni</td>
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<td></td>
<td>- Steiner</td>
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<td></td>
<td>- Tweed</td>
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<tr>
<td>Growth projections</td>
<td>Simulated Growth projections on lateral photos used for patient communication</td>
</tr>
<tr>
<td>Implant module</td>
<td>Simulates Generic implants only</td>
</tr>
<tr>
<td>3D imaging capabilities</td>
<td>None</td>
</tr>
<tr>
<td>Image Annotation</td>
<td>Text, paint, ellipse, pointer, select, draw, magnify, line, rectangle, polygon, ruler, protractor, smile library, smudge, brush</td>
</tr>
</tbody>
</table>

CS Orthodontic Imaging and CS OMS Imaging software
Mr. Daniel Hoefer  
Manager, Regulatory Affairs  
Carestream Dental LLC  
1765 The Exchange  
ATLANTA GA 30339

Re: K122427  
Trade/Device Name: CS Orthodontic Imaging and CS OMS Imaging software  
Regulation Number: 21 CFR 892.2050  
Regulation Name: Picture archiving and communications system  
Regulatory Class: II  
Product Code: LLZ  
Dated: August 7, 2012  
Received: August 10, 2012

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,

[Signed]
Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure
**Indications for Use**

CS Orthodontic Imaging and CS OMS Imaging software is indicated for use by orthodontists or oral maxillofacial surgeons and their clinical staff in storing and organizing images, including digital photographs and x-rays. The device includes the capability to trace a digital cephalometric radiograph, analyze the measurements taken and make growth or surgical predictions.

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**Concurrence of CDRH, Office of Device Evaluation**

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

[Signature]

Division of Radiological Devices