MAR 2 1 2002

510(k) Summary

K020635

1. Company Identification

Eastman Kodak Company
343 State Street
Rochester, NY 14650

Establishment Registration: 1317267

2. Contact Person

Susan Pate
Regulatory Affairs Associate
(716)-781-6314

3. 510(k) Summary Preparation Date

2/26/2002

4. Device Name

Trade Name: KODAK DirectView CR 800 System
KODAK DirectView CR 900 System

Common Name: Storage phosphor reader with software modification

5. Device Classification

Class II

6. Indications for Use

The KODAK DirectView CR 800 System and the KODAK DirectView CR 900 System are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiology applications.

7. Description of Device

The KODAK DirectView CR 800 is a single cassette computed radiography (CR) system while the KODAK DirectView CR 900 is an autoloading CR system. Each CR system contains a storage phosphor reader, CR cassette, HeNe laser, QA workstation with image processing software, and a DICOM network connection.

These CR systems are capable of reading the latent image formed on a storage phosphor imaging plate in a CR cassette and producing a digital image. The system scans the phosphor plate, communicates the image data to a host (e.g. soft copy review workstation or laser printer) and erases the residual image on the plate. An internal imaging plate eraser removes the residual image. The plate is then returned to the cassette, ready for the next exposure.

Software Modification

Anti-scatter grids are commonly used in radiography to reduce scattered x-rays and improve image contrast and signal-to-noise ratio. The new software modification uses a grid detection and suppression algorithm to reduce line artifacts caused by the use of anti-scatter grids. These grid artifacts, when present, can be distracting to radiologists when reviewing CR images, particularly in soft copy. The user may select the amount of grid suppression to be applied within a range of 0-15 through preference settings at the operator console of the CR system.

All other features and capabilities of the CR 800 and the CR 900 system remain unchanged by this software modification.

8. Substantial Equivalence

The analytical characteristics of the grid detection and suppression algorithm were evaluated for a wide variety of grids commonly in use in the medical community. The algorithm was effective at reducing grid induced artifacts.

An evaluation was performed, with hard copy CR images, to study the impact of grid suppression on diagnostic image quality. The effect of grid suppression on images with and without grids was assessed across several grid frequencies, orientations and a variety of radiographic exams (e.g. chest, abdomen, spine, shoulder, pelvis). On a scale of 1 to 9 with 7 being acceptable for interpretation, ten radiologists rated the exams as acceptable for interpretation or better when grid suppression was applied. Average scores ranged from 7.2 with no grid suppression to 7.7 with maximum grid suppression applied. The differences in rating for with and without grid suppression were not clinically significant.

The KODAK DirectView CR 800 and KODAK DirectView CR 900 with grid suppression are substantially equivalent to the previously cleared device [K923544].

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

Ms. Susan Pate
Regulatory Affairs Associate
Eastman Kodak Company
343 State Street
ROCHESTER NY 14650

AUG 23 2013

Re: K020635
Trade/Device Name: Kodak DirectView CR 800 and CR 900 Systems
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 26, 2002
Received: February 27, 2002

Dear Ms. Pate:

This letter corrects our substantially equivalent letter of March 21, 2002.

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,

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

Enclosure

Attachment 9 - Indications for Use

510(k) Number (if known): [redacted] K020635

Device Name: KODAK DirectView CR 800 and KODAK DirectView CR 900 Systems

Indications of Use: The KODAK DirectView CR 800 System and the KODAK Direct View CR 900 System are compact laser scanners capable of reading the latent image formed on a storage phosphor imaging plate and producing a digital image for projection radiography applications.

Concurrence of CDRH, Office of Device Evaluation

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

David G. Seymour

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020635