MAY 2 4 2004

510(k) Summary

K040372

1. Company Identification

Eastman Kodak Company
343 State Street
Rochester, NY 14650

Establishment Registration: 1317267

2. Contact Person

Susan Pate
Regulatory Affairs Associate
(716)-724-4302

3. 510(k) Summary Preparation Date

02/12/2004

4. Device Name

Trade Name: KODAK DIRECTVIEW CR Cassette / GP / 15 x 30 cm

Common Name: CR 15 x 30 cm Cassette

5. Device Classification

Class II

6. Indications for Use

The KODAK DirectView CR cassette holds a storage phosphor screen which is exposed by radiographic equipment for the recording of a patient radiation pattern. The cassette is loaded into a compact laser scanner capable of reading the latent image. The Kodak DirectView CR 15 x 30 cm cassette and storage phosphor screen can be used for general radiology and dental panoramic radiography applications.

7. Description of Device

The Kodak DirectView CR 15 x 30 cm cassette size is designed to perform general radiography and panoramic dental exams when used with the Kodak DirectView CR 850 and CR 950 systems. The cassette system (cassette and storage phosphor screen adhered to the cassette plate) can be used in common

dental panoramic x-ray dental units designed to accept cassettes that meet the ISO 4090 standard. The CR cassette is a standard x-ray diagnostic cassette used for computed radiography.

The panel materials are consistent with the current design of the CR cassette and include Corus Hylite and Toray Panel. The Corus Hylite panel includes two layers of aluminum, with polypropylene (plastic) in the middle, and is covered with Omnova (clear vinyl with printing on the second surface). On the tube side of the cassette there is Toray Carbon Fiber Panel that consists of four layers of carbon fiber. The storage phosphor plate is attached to the honeycomb panel. The lead mylar that is in place under the phosphor layer of the screen was removed in the CR 15 x 30 cm cassette in order to accommodate Automatic Exposure Control (AEC) in dental x-ray units.

The image processing software algorithm will not be modified for the CR 15 x 30 cm cassette, and remains the same as the image processing software previously cleared for Kodak DirectView CR 800 and CR 900 Systems (K020635, March 21, 2002).

8. Substantial Equivalence

The KODAK DirectView CR 15 x 30 cm cassette is substantially equivalent to the Kodak Ektascan SP Cassette (K925997), previously cleared on December 17, 1992. The Kodak Ektascan SP Cassette is currently marketed as the Kodak DirectView CR Cassette. The new cassette size is identical in function and performance to the currently marketed Kodak DirectView CR cassette.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 2 4 2004

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

Re: K040378
Trade/Device Name: KODAK DirectView CR Cassette/GP/15x30 cm
Regulation Number: 21 CFR 892.1850
Regulation Name: Radiographic film/cassette changer
Regulatory Class: II
Product Code: 90 IXA
Dated: February 13, 2004
Received: March 16, 2004

Dear Ms. Pate:

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 either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

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 Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Attachment 1 – Intended Use and Indications for Use

510(k) Number(s) (if known): K040378

Device Name: KODAK DirectView CR Cassette / GP / 15 x 30 cm

Indications of Use:
The KODAK DirectView CR cassette holds a storage phosphor screen which is exposed by radiographic equipment for the recording of a patient radiation pattern. The cassette is loaded into a compact laser scanner capable of reading the latent image. The Kodak DirectView CR 15 x 30 cm cassette and storage phosphor screen can be used for general radiology and dental panoramic radiography applications.

Concurrence of CDRH, Office of Device Evaluation

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K040378