DEC 15 2005

K053173

510(k) Summary

as required by 807.92

1. Company Identification

KONICA MINOLTA MEDICAL & GRAPHIC, INC.
2970 Ishikawa-machi
Hachioji-shi, Tokyo
192-8505, Japan
Tel: +81-426-60-9607
Fax: +81-426-60-9588

2. Official Correspondent

Masafumi Saito(Mr.)
Department TS
Advanced Technology Division
R & D Center

3. Date of Submission

November 4th, 2005

4. Device Trade Name

DS Cassette

5. Common Name

Radiographic film cassette

6. Classification

Radiographic film cassette, Class II per 21 CFR 892. 1850.

7. Applicable Standard

Voluntary standard to which the DS Cassette conforms is: ISO 4090:2001

A certification by a manufacturer of the cassette, Okamoto Manufacturing Co., Ltd. (Registration Number: 3004768771) is attached.

8. Intended Use

The DS Cassette is intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film. It is not intended for mammography use.

9. Description of Device

The DS Cassette is intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film. The cassette is in a family of film sizes. The sizes are as follows;
35 x 43cm, 35 x 35cm, 40 x 40cm, 30 x 40cm, 30 x 35cm, 24 x 30cm,
24 x 24cm, 20 x 40cm, 18 x 43 cm, 18 x 24cm, 15 x 40cm, 15 x 30cm,
14 x 17inch, 14 x 14inch, 12 x 15inch, 11 x 14inch, 10 x 12inch, 8 x 10inch,
6.5 x 8.5inch, 7 x 17inch
The exposed film is taken out from the Cassette manually or automatically for processing by X-ray film processor such as Konica DS-7 automatic X-ray film processor, 510(k) number K931316.
For more information, please refer to the attachments.

10. Substantial Equivalence to Predicate Device

The DS Cassette is substantially equivalent to Konica Mammography Cassettes; Models CM and CM DS-7, 510(k) number: K963914.

11. Technological Characteristics

The technological characteristics of the DS Cassette are the same as those of the predicate device. The product specifications by a manufacturer of the cassette, Okamoto Manufacturing Co., Ltd. (Registration Number: 3004768771) is attached.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2005

Mr. Shinichi Yamanaka
Progress Secretary
Cosmos Corporation
319 Akeno, Obata-cho, Ise-shi
Mie-ken, 519-0501
JAPAN

Re: K053173
Trade/Device Name: DS Cassette
Regulation Number: 21 CFR 892.1850
Regulation Name: Radiographic film cassette
Regulatory Class: II
Product Code: IXA
Dated: November 4, 2005
Received: November 15, 2005

Dear Mr. Yamanaka:

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 (Premarket Approval), 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 this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.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

Indications for Use

510(k) Number (if known) : K053173

Device Name : DS Cassette

Indications For Use:

The DS Cassette is intended for use during diagnostic x-ray procedures to hold a radiographic film in close contact with an x-ray intensifying screen and to provide a light-proof enclosure for direct exposure of radiographic film. It is not intended for mammography use.

Prescription Use ✓ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K053173