K061999

510(k) Summary

as required by 807.92

AUG 15 2006

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

Kouji Matsushima (Mr.)
Manager
Advanced Technology Division
R&D Center

3. Date of Submission

July 10, 2006

4. Establishment Registration No.

3003769120

5. Device Trade Name

Dry Laser Imager, DRYPRO Model 832

6. Common Name

Medical Image Hardcopy Device

7. Classification

Class Ⅱ, 21 CFR 892. 2040, Medical image hardcopy device

8. Product Cord

90 LMC

9. Predicate Device

Konica Laser Imager, DRYPRO Model 771, 510(K) No.: K032681
Comparison of the principal characteristics of the two devices which are pertinent to Specification performance is attached.

10. Description of Device

The Dry Laser Imager, DRYPRO Model 832 is a Laser Imager to receive image data from diagnostic equipment such as CT, MRI, DSA and other medical devices and print them on medical dry-film.

The device consists of film supplying unit, film transferring unit, exposing unit, heat-developing unit, operating unit, power supplying unit and main control unit.
This product employs semiconductor laser for laser scanning, but it complies with the Federal Performance Standard 21 CFR Part 1040.10.

This device has no patient contacting materials and is intended to be used by trained personnel only.
The output of the device is evaluated by additionally trained personnel capable of sufficient review to afford identification and intervention in case of malfunction.

11. Intended Use

The Dry Laser Imager, DRYPRO Model 832 is intended to be used to receive image data from diagnostic equipment such as CT, MRI, DSA and other medical devices and print them on medical dry-film. The output image is not a high resolution and DRYPRO Model 832 is not intended for use with FFDM systems.

12. Compliance Standard

UL60601-1, UL-825-1
IEC60601-1, IEC60601-1-2, IEC60825-1, 21 CFR 1040.10, DICOM

Item	Approved Medical Device	Medical Device Applied for Approval
Applicant,etc.		
Company	Konica Minolta Medical&Graphic Inc.	Konica Minolta Medical&Graphic Inc.
Product Name	DRYPRO model 771	DRYPRO model 832
Approval No.	K032681	
Configuration	The device consists of film supplying unit and film transferring unit and exposing unit and heat-developing unit and operating unit and power supplying unit and main control unit	The device consists of film supplying unit and film transferring unit and exposing unit and heat-developing unit and operating unit and power supplying unit and main control unit
Principle of Operation	Select the printing format on the contoroller. Push the storing key in order to store the printing images and push the printing key. So the film is picked up and then is transferred exposing unit. This printing images is exposed on that film there by laser and optical devices. Exposed film is transferred to heat-developing unit and photo-finished, then ejected from	Select the printing format on the contoroller. Push the storing key in order to store the printing images and push the printing key. So the film is picked up and then is transferred exposing unit. This printing images is exposed on that film there by laser and optical devices. Exposed film is transferred to heat-developing unit and photo-finished, then ejected from
Specification		
Laser Source	Laser Diode [LD] (810nm)	Laser Diode [LD] (785nm)
Laser Power	100mW (Maximum Output)	240mW (Maximum Output)
Laser Modulator	Direct driving modulater	Direct driving modulater
Film Type	Konica Medical Imaging Film (SD-P & SD-Pc)	Konica Medical Imaging Film (SD-P & SD-Pc)
Film Sizes	14"x 17",14"x 14",11"x 14"	14"x 17",14"x 14",11"x 14",10"x 12",8"x 10"
Film Supply	1 units	1 unit or 2 units (125 or 50 film on each) for installation of Optional Supply
Interface	10/100base-TX, 4network ports maxmum	10/100/1000base-TX, 4network ports maxmum
Protocol	Digital Imaging and Communications in Medicine [DICOM] version 3.0	Digital Imaging and Communications in Medicine [DICOM] version 3.0
	Print service class	Print service class
Image Data Storage	one Hard Disk Drive	outside PC
Image Formatting	1,2,4,6,9,12,15,16,20,24,25,30,35,36,42, and 48 frame formats, and mixed formats available. (Possible formats limited according to the image data)	1,2,4,6,9,12,15,16,20,24,25,30,35,36,42, and 48 frame formats, and mixed formats available. (Possible formats limited according to the image data
Pixel Size	78.6 micro-meters minimum	78.6 micro-meters minimum
Density Resolution	14bits / pixel	14bits / pixel
Cycle Time	30 sec.	40 sec.
Test Pattern	Pre-programmed SMPTE pattern	Pre-programmed SMPTE pattern
Smoothing	Choice of Pixel replication, Bi-linear. Spline functions via network	Choice of Pixel replication, Bi-linear. Spline functions via network
Image Rotation	Choice of 0 (normal), 90 degrees via network	Choice of 0 (normal), 90 degrees via network
Exposure Setting	8 types / port via network	8 types / port via network
Image Borders	Choice of black or clear via network	Choice of black or clear via network
Image Framing	Choice of framing or no framing via network	Choice of framing or no framing via network
Print Developing	Choice between negative and positive printing via network	Choice between negative and positive printing via network
Character Input	Data and message data printed in margins via network	Data and message data printed in margins via network
Copying	99 copies per print maximum via network	99 copies per print maximum via network
Controller Display	Backlight liquid-crystal display (20places, 2lines)	Backlight liquid-crystal display (20places, 2lines)
External Dimensions	W630mm x D600mm x H1125mm	W599mm x D585mm x H570mm
Weight	Approx. 175Kg	Approx. 95Kg
Power Source	AC100~120V 50/60Hz 、AC220~240V 50Hz	AC100~120V 50/60Hz 、AC220~240V 50Hz
Power Consumption	1020VA maximum (destination of USA)	1200VA maximum (destination of USA)
Work Space Environmen	15~30℃;30~75%RH	15~30℃;30~75%RH
Magnetic Resistance	Up to 5 gauss	Up to 5 gauss
Exhaust Heat	Approx. 950kJ / hour	Approx. 1200kJ / hour
Optional Equipment	-	1bin Supply
Warranty	12months from the time of installation	12months from the time of installation
Purpose of use	The device is intended for the use at the X-ray department of the hospital, etc. the device that will acquire data from diagnostic equipment and then print the data onto laser imaging film.	The device is intended for the use at the X-ray department of the hospital, etc. the device that will acquire data from diagnostic equipment and then print the data onto laser imaging film.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

AUG 15 2006

Mr. Koji Matsushima
Manager
Konica Minolta Medical & Graphic, Inc.
TSG, Advanced Technology Division, R&D Center
2970 Ishikawa-machi,
Hachioji-Shi, Tokyo, 192-8505
JAPAN

Re: K061999
Trade/Device Name: Dry Laser Imager, DRYPRO Model 832
Regulation Number: 21 CFR 892.2040
Regulation Name: Medical image hardcopy device
Regulatory Class: II
Product Code: LMC
Dated: July 10, 2006
Received: July 14, 2006

Dear Mr. Matsushima:

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.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
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) : K061999

Device Name : Dry Laser Imager, DRYPRO Model 832

Indications for Use:

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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)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K061999