

MAR 27 2000

510 (k) SUMMARY OF 21 CFR 807.92
FOR
MODEL MCA-601 C-ARM MOBILE
FLUOROSCOPIC SYSTEMS, IMAGE INTENSIFIED

K 993896

1.0 Device Name :

Trade Name : C-Arm Mobile X-Ray Systems

2.0 Reason for Submittal:

Model Name Change

3.0 Submitting Establishment :

Medison Radiology Systems, Inc
151 South Pfingsten Road, Unit V
Deerfield, Illinois 60015

Establishment Registration No. : 1424247

Corresponding Official : John W. Lee, President

847-291-0999

Manufacturer : MedisonAcoma Co., Ltd
22-8, 3-Chome Hongo, Bunkyo-ku
Tokyo, Japan

4.0 Panel and Device Classification :

Panel: Fluoroscopic Systems, Image Intensified
Classification: II

5.0 Description:

High frequency X-ray generator and Image intensifier systems are mounted on C-arm transport mobile base. See Appendix "A" for the system configuration and labeling data.

6.0 Intended Use :

Producing fluoroscopic and general radiographic images for patient treatment and diagnosis. Especially being used during special procedures.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 27 2000

John W. Lee
President
Medison Radiology Systems, Inc.
151 South Pfingsten Road, Unit V
Deerfield, IL 60015

Re: K993896
MCA-601, C-Arm Mobile
Dated: February 28, 2000
Received: March 1, 2000
Regulatory class: II
21 CFR 892.1650/Procode: 90 JAA
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Lee:

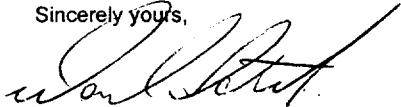
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4591. 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 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure(s)

510 (k) Number (If known) : K993896
Device Name : MCA-601, C-arm mobile

Indication of Use :

The MCA-601, C-Arm Mobile is used for providing fluoroscopic and radiographic images of patient anatomy, especially during special procedures in a hospital or medical clinics.

The fluoroscopic mode of operation is very useful to the attending physician to see the images in real time without the need to develop individual films.

(Please do not write below this line - continue on the another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓
(Per 21 CFR 801. 109)

OR Over - The - Counter - Use _____
(Optional Format 1-2-9)

David A. Segerson
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices

510(k) Number K993896