AUG 3 1 2001

K012663

**EXHIBIT 2**

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|---|---|
| SEDECAL SA<br>Pelaya 9- Poligono Industrial Rio De Janeiro<br>28110 –Algete<br>Madrid Spain<br>Tel (34) 91-628 0544/91-628 1592<br>Fax (34) 91-628 0574<br>(Foreign Manufacturer) | SEDECAL USA, Inc.<br>2910 N. Arlington Heights Rd.<br>Arlington Heights Illinois 60006<br>Tel 847-394-6960<br>Fax 847-394-6966<br>(Initial Importer) |

August 8, 2001

**Contact:** Gary Fromberg, Official Correspondent

## 510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   **Proprietary-Trade Name:** "Easy Moving™" Mobile X-ray Unit (Model SM-HF)
   **Classification Name:** X-Ray, Mobile, Product Code 90 IZL
   **Common/Usual Name:** Stationary X-Ray System

2. **Equivalent legally marketed devices** This product is similar in function to the IROM IMAGING, INC MXR-2000 MOBILE X-RAY UNIT K010304

3. **Indications for Use (intended use)** The "Easy Moving™" Mobile X-ray Unit (Model SM-HF) is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

4. **Description of the Device:** The "Easy Moving™" Mobile X-ray Unit (Model SM-HF)" is a mobile unit which operates from 120 V 50-60~ AC or batteries. It is easy to operate and permits a swift radiographic procedure, a feature which applies to all conventional exposure techniques on all parts of the body. The system is composed of a base unit housing the high voltage generator and controls and a turnable arm with rotatable tube head. It allows one to take exposures of patients in standing, sitting or laying position. Owing to its compact design "Easy Moving™" Mobile X-ray Unit is a low-cost radiography system which takes up little space and is quick to set up and operate.

5. **Safety and Effectiveness, comparison to predicate device.** The results of bench and user testing indicates that the new device is as safe and effective as the predicate devices.

## 6. Substantial Equivalence Chart, "Easy Moving™" Mobile X-Ray System

| Characteristic | IROM IMAGING, INC MXR-2000 MOBILE X-RAY UNIT K010304 | "Easy Moving™" Mobile X-Ray System |
|---|---|---|
| Intended Use: | Intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position. | SAME |
| Performance Standard | 21 CFR 1020.30 | SAME |
| Electrical safety | Electrical Safety per Underwriters Laboratories Standard UL-2601(IEC-60601) and IEC 60601, Underwriters Laboratories Standard UL187: UL Standard for Safety for X-Ray Equipment, | SAME, plus EMC: IEC 60601-1-2 |

## 7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Sedecal USA that the "Easy Moving™" Mobile X-ray Unit is as safe and effective as the predicate device, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 31 2001

SEDECAL USA, Inc.
% Mr. Daniel Kamm
Kamm & Associates
P.O. Box 7007
DEERFIELD IL 60015

Re: K012663
Easy Moving™ Mobil X-ray Unit (Model SM-HF)
(Mobil X-ray System)
Dated: August 9, 2001
Received: August 13, 2001
Regulatory Class: II
21 CFR 892.1720/Procode: 90 IZL

Dear Mr. Kamm:

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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this 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, 4,xxx, 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" (21 CFR 807.97). 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

510(k) Number (if known): K012663

Device Name: _____

Indications For Use:

**Indications for Use (intended use)** The "Easy Moving™" Mobile X-ray Unit (Model SM-HF) is intended for use by a qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of the skull, spinal column, chest, abdomen, extremities, and other body parts. Applications can be performed with the patient sitting, standing, or lying in the prone or supine position.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K012663

(Optional Format 1-2-96)