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EXHIBIT 2

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

August 2, 2001

Contact: Gary Fromberg, Official Correspondent

510(k) Summary of Safety and Effectiveness

1. **Identification of the Device:**
   Proprietary-Trade Name: "Optima URS" Universal Radiographic System
   Classification Name: Stationary X-Ray System, Product Code 90 KPR
   Common/Usual Name: Stationary X-Ray System

2. **Equivalent legally marketed devices** This product is similar in function to the Siemens Multix Stationary X-Ray System (K001201)

3. **Indications for Use (intended use)** The "Optima URS" Universal Radiographic System 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 "Optima URS" is a stationary unit which operates from 120 V 50-60~ AC. Optima URS is a universal swivel arm X-ray system. 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 floor-to wall column and a turnable arm with variable high center. It allows one to take exposures of patients in standing, sitting or laying position. Owing to its compact design Optima URS is a low-cost radiography system which takes up little space and is quick to install.

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.

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6. Substantial Equivalence Chart, "Optima URS"

Characteristic	Siemens Multix Stationary X-Ray System (K001201)	"Optima URS" Universal Radiographic 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, CE Marking Requirements, ISO 9001.	SAME, plus EMC: EN50081-1 Residential commercial, light industry general - EMC emission EN50082-1 Residential, commercial, light industry general - EMC immunity, EN60950 Safety of IT and electrical business equipment

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Sedecal USA that the "Optima URS" Universal Radiographic System 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

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

Re: K012546
Trade/Device Name: Optima URS
Universal Radiographic System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: 90 KPR
Dated: August 6, 2001
Received: August 7, 2001

Dear Mr. Kamm:

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 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 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, 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" (21 CFR Part 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

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j) Indications for Use

510(k) Number K012546

Device Name: "Optima URS" Universal Radiographic System

Indications for Use: The "Optima URS" Universal Radiographic System 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.

_____ _____ _____ _____ _____ _____ _____ _____ _____

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 K012546