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K020436

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EXHIBIT 2

510(k) Summary of Safety and Effectiveness

SEDECAL SA 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)	SEDECAL USA, Inc. 2910 N. Arlington Heights Rd. Arlington Heights Illinois 60006 Tel 847-394-6960 Fax 847-394-6966 (Initial Importer) Contact: Gary Fromberg

February 5, 2002

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: Models SP-HF-2.8 and SP-HF-4.0 Portable X-ray Units
   Classification Name: Mobile X-ray system, Product Code 90 IZL
   Common/Usual Name: Portable general purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: This product is similar in function to the MinXray HF100H (a pre-amendments device)

3. Indications for Use (intended use) Models SP-HF-2.8 and SP-HF-4.0 are 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: Models SP-HF-2.8 and SP-HF-4.0 are a portable units which operate from 120 V 50-60~ AC. The unit utilizes a newly designed high frequency inverter and can be either mounted to a tripod or support arm or can be hand held. The usual safety precautions regarding the use of x-rays must be observed by the operator.

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 device.

6. Substantial Equivalence Chart, Models SP-HF-2.8 and SP-HF-4.0

Characteristic	MinXray HF100H	Models SP-HF-2.8	Model SP-HF-4.0
Intended Use:	Potable general purpose diagnostic X-ray unit	SAME	SAME
Physical characteristics:			
Size	8.75"H x 9.5" W x 15.35" D.	8.7 H x 10.4" W x 16.5" D	8.7 H x 10.4" W x 16.5" D
Weight	40.9 lbs	33 lb	33 lb
Energy Source:	120 v 50-60~ AC	90 to 285 VAC (50-60 Hz)	90 to 285 VAC (50-60 Hz)
User Interface	Up-Down pushbuttons for three kVp selections and exposure time selections with LED indicators	Up-Down pushbuttons for kVp and mAs. kVp adjustable in 1 kVp steps	Up-Down pushbuttons for kVp and mAs. kVp adjustable in 1 kVp steps
Exposure times	0.08-2.00 Sec. In 192 steps	0.002-10 sec 38 steps	0.001-10 sec 41 steps
Ma.	20 mA	5,.6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50	5, 6.4, 8, 10, 12.5, 16, 20, 25, 32, 40, 50, 64, 80, 100
KvP	100 KvP	110 KvP	115 KvP
Standards and Safety characteristics:			
Performance Standard	21 CFR 1020.30	SAME	SAME
Electrical safety:	UL 2601, IEC 60601-1	SAME	SAME

7. Conclusion

After analyzing both bench and user testing data, it is the conclusion of Sedecal that the Models SP-HF-2.8 and SP-HF-4.0 are as safe and effective as the predicate device, have 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

FEB 2 2 2002

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

Re: K020436
Trade/Device Name: Models SP-HF-2.8 and SP-HF-4.0 Portable X-ray Unit
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobil x-ray system
Regulatory Class: II
Product Code: 90 IZL
Dated: February 6, 2002
Received: February 8, 2002

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

j) Indications for Use

510(k) Number K020436

Device Name: Models SP-HF-2.8 and SP-HF-4.0 Portable X-ray Units

Indications for Use: Models SP-HF-2.8 and SP-HF-4.0 Portable X-ray Units are intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays.

_____ _____ _____ _____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Janet C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K020436