DEC 0 4 2008

510(k) Summary

K08 3109

SUINSA
C/Primavera 39 - Polígono Industrial 'Las Monjas' 28850
Torrejón de Ardoz Madrid / Spain
· Tel.: +34 91 6559500
· FAX : +34 91 6755253
Prepared October 8, 2008
Contact: Jose Maria Ortega, CEO

1. Identification of the Device:
   Proprietary-Trade Name: Suinsa Diagnostic X-Ray System (STATIONARY).
   Classification Name: Stationary X-ray system,
   Product Codes Product Code 90 KPR
   Common/Usual Name: General purpose diagnostic X-ray Unit.

2. Equivalent legally marketed devices: Almana Medical Radvision ET Diagnostic X-Ray Systems K082064

3. Indications for Use (intended use) This X-Ray 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: This system is a combination of the following Suinsa manufactured components:
   - The Hercules Generator, with models from 32 to 80 kW.
   - The NOVA Ceiling Mounted Tube Stand
   - The NET4000 series X-ray table
   - The NBS2100 Bucky Wall Stand

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

6. Substantial Equivalence Chart

Characteristic	**Almana Medical Radvision ET Diagnostic X-Ray Systems K082064**	**Suinsa Diagnostic 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
Configuration	Ceiling Mount (made by Suinsa)	SAME
Generator	High Frequency Sedecal	High Frequency Suinsa
Maximum output	Various models, 32 to 80 kW	SAME, 32 to 80 kW
Image Acquisition	Film	Film.
Collimator	RALCO	SAME
Safety	UL Listed	CSA listed to US Standards
Standards	US Performance Standard + applicable IEC standards	SAME

7. Conclusion

After analyzing bench and standards testing data, it is the conclusion of Suinsa that the Suinsa Diagnostic X-Ray Systems is as safe and effective as the predicate devices, have few technological differences, and have no new indications for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2008

Suinsa
% Mr. Daniel Kamm, P.E.
Principal Consultant
Kamm & Associates
PO Box 7007
DEERFIELD IL 60015

Re: K083109
Trade/Device Name: Suinsa Diagnostic X-Ray System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: October 15, 2008
Received: October 21, 2008

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 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). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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,

Joyce M. Whang, Ph.D.
Acting 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): K083109

Device Name: Suinsa Diagnostic X-Ray System

Indications For Use:

The Suinsa Diagnostic X-Ray 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.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K083109