

K071193

MAY 30 2007

**EXHIBIT 2**  
**510(k) Summary**



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**Contact: Carrie L. Brancart, Quality Manager**

**Date Prepared: May 13, 2007**

1. **Identification of the Device:**  
Proprietary-Trade Name: Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems  
Classification Name: Stationary X-ray system,  
Product Codes Product Code 90 KPR and MQB  
Common/Usual Name: General purpose diagnostic X-ray Unit.
2. **Equivalent legally marketed devices:** This notification is for a MODIFIED device. This device COMBINES two 510(k) cleared devices, the SEDECAL Universal Radiographic Systems K012546 AND the Vidar 2000 Digital Radiographic Detector, K070563. This combination is functionally identical to a SEDECAL cleared device, Sedecal URS LP X-Ray Units with Digital Detector, K042876..
3. **Indications for Use (intended use)** Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems are indicated for use in generating radiographic images of human anatomy. It has a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures. The Vidar Vision 3000 and Vidar Vision 4000 is not indicated for diagnostic X-ray mammography.
4. **Description of the Device:** The VIDAR VISION 3000 Digital Radiography system is an affordable DR (Digital Radiographic) solution designed for smaller radiography environments, including imaging centers, orthopedic practices, small hospitals, and outpatient areas of hospitals. The VIDAR VISION 3000 is the first truly affordable, full-featured DR system, providing a total solution for all digital radiographic examinations. The VIDAR VISION 3000 features high image quality, rapid image acquisition, improved productivity, and ease of use. The flexible system features a 3K detector for the high-resolution imaging needs of busy radiology centers, orthopedic practices, and hospitals. VIDAR's new VISION DR product line also includes the VISION 4000 system, with a 4K detector that is ideal for higher volume settings.
5. **Safety and Effectiveness, comparison to predicate device.** The results of bench, user, and standards testing indicates that the new device is as safe and effective as the predicate devices.

6. Substantial Equivalence Chart, Vidar Vision 3000 and Vidar Vision 4000

<b>Characteristic</b>	<b>Sedecal URS X-Ray Units with Digital Detector K042876</b>	<b>Vidar Vision 3000 and Vidar Vision 4000 Combines two cleared devices: K070563 AND K012546</b>
Intended Use:	General purpose diagnostic X-ray unit	SAME
User Interface	Depends on Control Console option chosen. Mainly dedicated touch controls	Software Driven Touch Panel LCD, + remote control unit + remote console
Maximum output	Depends on model of generator chosen. Models available from 30 kW to 64 kW	50, 64, and 80 kW
Image Acquisition	Digital: CANON CXDI-50G. K031447	Digital: Vidar Digital Radiographic Detector K070563
Digital Panel Size	Up to 14" x 17" active area	Vision 3000/4000: Active image size: 16 x 16 inches (40cm x 40cm)
Digital Resolution	160 x 160 microns pixel pitch, with approximately 6 million pixels	Vision 3000: 160 Micron: 3056 x 3056 (9 megapixels)  Vision 4000: 120 Micron 4096 x 4096 (16 megapixels)
Method of Control	Dedicated push button Controls	Software Driven Touch Panel LCD
Collimator	Manual R302/A	Ralco R302L/A DHHS

7. Conclusion After analyzing bench, user, and standards testing data, it is the conclusion of Vidar Systems that the Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems are 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.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Vidar Systems Corporation  
% Mr. Daniel Kamm  
Principal Consultant  
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P.O. Box 7007  
DEERFIELD IL 60015

AUG 23 2013

Re: K071193

Trade/Device Name: Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary x-ray system  
Regulatory Class: II  
Product Code: MQB  
Dated: April 24, 2007  
Received: April 30, 2007

Dear Mr. Kamm:

This letter corrects our substantially equivalent letter of May 30, 2007.

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 class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

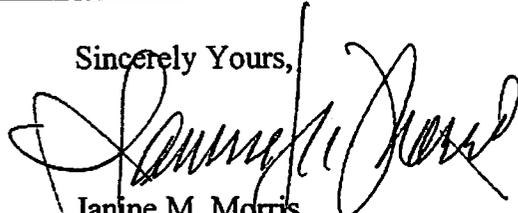
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,



Janine M. Morris  
Acting Director  
Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K071193

Device Name: Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems

### Indications For Use:

Vidar Vision 3000 and Vidar Vision 4000 X-Ray Systems are indicated for use in generating radiographic images of human anatomy. It has a Solid State X-ray Imaging system intended to replace radiographic film/screen systems in all general-purpose diagnostic procedures.

The Vidar Vision 3000 and Vidar Vision 4000 is not indicated for diagnostic X-ray mammography.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

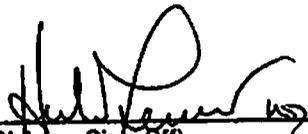
Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)  
Division of Reproductive, Abdominal, and  
Radiological Devices  
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