

SECTION 5. 510(K) SUMMARY**Submission
Correspondent:**

5-Star Medical, Inc.

FEB 24 2009

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Email: terry@pvmed.net
Contact: Terry L. Ancar**Submission Sponsor:**5-Star Medical, Inc.
11515 Prosperous Dr.
Odessa, FL 33556Phone: (727) 753-0410
Fax: (727) 376-2868
Email: terry@pvmed.net
Contact: Terry L. Ancar**Date summary prepared:**

October 30, 2008

Device trade name:

RadStar Digital Imaging System

Device common name:

Solid State X-ray Imager (Flat Panel/Digital Imager)

Device classification name:

MQB at 21 CFR Part 892.1650

**Legally marketed devices
to which the device is
substantially equivalent:**K081648
Canon CXDI-60GK024147
Varian PaxScan 4030**Description of the device:**

The RadStar Digital Imaging System consists of two components, a solid state x-ray imager and software for viewing the captured images on a Windows-based computer. The device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. The RadStar Digital Imaging System will display high quality images in less than 5 seconds over a wide range of X-Ray dose settings.

Intended use of the device: The RadStar DDR Digital Imaging System is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. The device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

Technological characteristics:

The technological characteristics between the predicate and proposed devices are identical. There is no difference in fundamental scientific technology.

Conclusions:

There are no significant differences between the RadStar Digital Imaging System and the predicate devices and therefore, the RadStar Digital Imaging System does not raise any questions regarding safety and effectiveness.

The RadStar Digital Imaging System, as designed, is as safe and effective as the predicate device, and the device is determined to be substantially equivalent to the referenced predicate device currently on the market.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

5 Star Medical, Inc.
% Mr. Terry L. Ancar
President
Porta Vision Medical
P.O. Box 641606
KENNER LA 70065

FEB 24 2009

Re: K083645

Trade/Device Name: RadStar DDR Digital Imaging System
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: January 12, 2009
Received: January 21, 2009

Dear Mr. Ancar:

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.

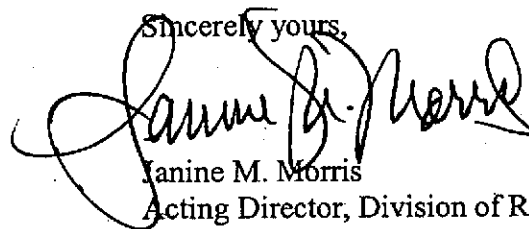
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4. INDICATIONS FOR USE STATEMENT**510(k) Number:**K083645**Device Name:**

RadStar DDR Digital Imaging System

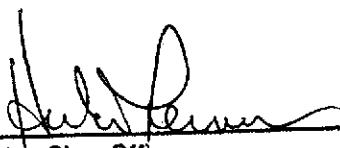
Indications for Use:

The RadStar DDR Digital Imaging System is intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is intended for incorporation into a complete x-ray system by qualified x-ray service personnel. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

Prescription Use X
(Part 21 CFR 801 Subpart D)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083645