K111312

JUL 13 2011

510(k) Summary

This summary of 510(K) – safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: 05/06/2011

1. Company making the submission

	Submitter
Name	SEHYUN Co., Ltd.
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2. U.S Agent/Contact Person

LK Consulting Group
951 Starbuck St. Unit J, Fullerton, CA 92833
Priscilla Chung
Phone: 714-869-3080 Fax: 714-409-3357
Email: info@LKconsultinggroup.com

3. Device

- Trade Name: SanteView-3001C
- Common Name: Digital Flat Panel X-ray Detector
- Classification: Class II
- Classification regulation: 21 CFR 892.1650
- Product Code: MQB

4. Predicate Device:

- PaxScan 4030 Medical Digital Imaging System by Varian Medical System (K024147)
- CXDI-60C by Canon USA, Inc.(K091545)
- Pixium 4600 (cleared under the name, Philips Bucky Vision) by Trixell (K982795)

5. Description:

The SanteView-3001C is a solid state x-ray imager which has 440x440mm

imaging area. The SanteView-3001C intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo-detectors that create an electrical signals. After the electrical signals are generated, it is converted to digital value, and the images will be displayed on monitors.

6. Indication for use:

The SanteView-3001C provides digital image capture for conventional film/screen radiographic examinations. The device is intended to replace radiographic film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications.

7. Comparison to substantially equivalent devices:

The proposed and the predicate devices utilize similar technology and materials, and are similar in design and construction.

8. Safety, EMC and Performance Data:

EMC testing was conducted in accordance with standard EN/IEC 60601-1-2: All test results were satisfactory. The result of concurrence study shows that the new device is safe and effective as the predicate device

9. Conclusion

SEHYUN Co., Ltd. concludes that the SanteView-3001C is substantially equivalent to the currently marketed devices. It does not introduce new indications for use, has the same technological characteristics and does not introduce new potential hazards or safety risks.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

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

JUL 13 2011

SEHYUN Co., Ltd.
% Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group
951 Starbuck St., Unit J
FULLERTON CA 92833

Re: K111312
Trade/Device Name: SanteView-3001C
Regulation Number: 21 CFR 892.1650
Regulation Name: Image-intensified fluoroscopic x-ray system
Regulatory Class: II
Product Code: MQB
Dated: May 6, 2011
Received: May 10, 2011

Dear Ms. Chung:

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,

Mary S. Pastel, Sc.D.
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): K111312

Device Name: SanteView-3001C

Indications for Use:

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Prescription Use ____√_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

(Division Sign-Off)
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety

510(k) Number K111312