# 510(k) Summary
(K120020)

MAY - 4 2012

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

Date: May 2, 2011

**Company and Correspondent making the submission:**

Name – Vieworks Co., Ltd.

Address – #604, Suntechcity 2, 307-2, Sangdaewon-dong, Jungwon-gu, Seongnam-city, Gyeonggi-do, 462-806 South Korea

Telephone – +82-70-7011-6176

Fax – +82-31-737-4953

Contact – Ms. JungMi Kim / Compliance Officer

Internet – http://www.vieworks.com

**Proposed Device :**

Trade/ Proprietary Name : ViVIX-Shttp://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?start_search=1&ProductCode=MLR

| | |
|---|---|
| Common Name | : Digital Flat Panel X-ray Detector |
| Classification Name | : Solid State X-ray Imager |
| Product Code | : MQB |
| Device Class | : 2 |
| Regulation Number | : 892.1650 |

**Predicate Device :**

| | |
|---|---|
| Manufacturer | : VARIAN Medical Systems Inc. |
| Trade/ Proprietary Name | : Paxscan 4030 Medical Digital Imaging System |
| Common Name | : Flate Panel Digital Imager |
| Classification Name | : Solid State X-ray Imager |
| Product Code | : MQB |

| | |
|---|---|
| Device Class | : 2 |
| 510(k) Number | : K024147 |

| | |
|---|---|
| Manufacturer | : Samsung Mobile Display Co., Ltd. |
| Trade/ Proprietary Name | : LTX-240AA01-A |
| Common Name | : Digital Plate Panel X-ray Detector |
| Classification Name | : Solid State X-ray Imager |
| Product Code | : MQB |
| Device Class | : 2 |
| 510(k) Number | : K090742 |

**Description :**

ViVIX-S is a digital X-ray flat panel detector which has 43x43cm (FXRD-1717SA, FXRD-1717SB) or 35.8x43cm (FXRD-1417SA, FXRD-1417SB) imaging area.

The device intercepts x-ray photons and the scintillator emits visible spectrum photons that illuminate an array of photo (a-SI)-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.

This device should be integrated with an operating PC and an X-Ray generator. It can do to utilize as digitalizing x-ray images and transfer for radiography diagnostic.

Advanced digital imaging process allows considerably efficient diagnosis, all kind of information management, sharing of image information on network.

**Intended use :**

ViVIX-S is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography and/or for fluoroscopy.

**Comparison with predicate device:**

The imaging principle, intended use, technology and materials of ViVIX-S are substantially equivalent to the predicated devices, Paxscan 4030R of VARIAN Medical Systems Inc. and LTX240AA01-A of Samsung Mobile Display Co., Ltd. for the specified indications and satisfy the FDA regulatory requirements for a 510(k).

**Safety, EMC and Performance Data :**

▪ Electricl safety and EMC testing

Electrical, mechanical, environmental safety and performance testing according to standard IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard IEC 60601-1-2. All test results were satisfactory.

▪ Non-clinical study

The following non-clinical studies have been performed and the results show that the ViVIX-S is substantially equivalent to the predicate devices in these characteristics.

- Detective quantum efficiency(DQE), Quantum limited performance, Modulation transfer function(MTF), Effects of aliasing, Sensitivity linearity, Lag(Erasure thoroughness), Change in detection sensitivity, Dose requirement and reciprocity changes, Stability of device characteristics with time, Uniformity of device characteristic, Noise power spectrum(NPS), Spatial resolution, Minimum dose, Image Acquisition time, & Black level

▪ Clinical study

A concurrence study of 30 clinical images was conducted to compare the performance of the ViVIX-S to the predicate device (K090742). There were no significant differences between the images of the ViVIX-S and the predicate device images.

**Conclusions :**

Based on the results of the non-clinical and the clinical studies performed, we conclude that the ViVIX-S is effective, and substantially equivalent to the predicate devices.

END

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

Vieworks Co., Ltd.
Ms. Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
951 Starbuck Street, Unit J
FULLERTON CA 92833

MAY - 4 2012

Re: K120020
Trade/Device Name: ViVIX-S
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: April 24, 2012
Received: April 26, 2012

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,

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):** K120020

**Device Name:** ViVIX-S

**Indications For Use:**

ViVIX-S is indicated for digital imaging solution designed for general radiographic system for human anatomy. It is intended to replace film or screen based radiographic systems in all general purpose diagnostic procedures. Not to be used for mammography and/or for fluoroscopy.

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)

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

**510(k) Number** K120020