APR 0 3 2014

510(k) Summary
510(k) Number K133139

Viztek, LLC.
6491 Powers Avenue
Jacksonville, FL 32217
Phone: 800.366.5343, Fax: 904.448.9936
Date Prepared: February 22, 2014
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: ViZion Ultra
   Classification Name: Stationary X-Ray System, Product Code MQB, Regulation 892.1680
   Common/Usual Name: Digital X-Ray Receptor Panel

2. **Equivalent legally marketed device**: Viztek ViZion DR, K112661 and Viztek ViZion + DR, K123644.

3. **Indications for Use** ViZion Ultra is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion Ultra allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

4. **Description of the Device**: The ViZion Ultra system represents the straightforward integration of a new digital x-ray receptor panel (K110849) and our previously cleared software. This is a MODIFICATION of our clearances K112661 and K123644 wherein we have changed the supplier of the panel. Therefore a special 510(k) has been submitted. The ViZion Ultra is compatible with Sedecal SHF generators. Some manufacturers rebrand the Sedecal SHF generators, and these generators are compatible as well.

   ViZion Ultra is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD) ViZion Ultra is designed to perform digital radiographic examinations as a replacement for conventional film. This integrated platform provides the benefits of PACS with the advantages of digital radiography for a filmless environment and improves cost effectiveness. The major functions and principle of operation of the Viztek PACS and the new receptor panel were not changed. Our main predicate is ViZion + DR, K123644, wherein we combined our OPAL-RAD software with two new digital panels.

5. **Safety and Effectiveness, comparison to predicate device**. The results of clinical image inspection, bench, and test laboratory results indicates that the new device is as safe and effective as the predicate devices. Clinical images collected demonstrate equal or better image quality as compared to our predicates.

6. **Substantial Equivalence Chart**

Characteristic	Viztek ViZion DR K112661	ViZion + DR, K123644	Viztek ViZion Ultra K133139
Intended Use:	ViZion DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	ViZion + DR is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion + allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities	ViZion Ultra is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion Ultra allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

Characteristic	Viztek ViZion DR K112661	ViZion + DR, K123644	Viztek ViZion Ultra K133139
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.	This submission is for the Digital Panel and Software only, no generator or stand provided.
Digital Panel	Samsung LTX240AA01-A (K090742) Pixel size 143 µm 3072 x 3072 pixels	iRay Technology (Shanghai) Ltd. For the 17" x 17" panel: Pixel size 139 µm 3064×3072 pixels For the 14" x 17" panel: Pixel size 150 µm 2288×2800 pixels	Trixell Pixium Rad 4143 2880 (h) x 2880 (v) pixels, pitch 148 µm (h) x 148 µm (v) (K110849)
Software	Employs OPAL-RAD PACS image viewing and acquire interface software technology, K063337	SAME as K112661, outputs a DICOM image.	SAME as K112661, outputs a DICOM image.
DICOM	Yes	Yes	Yes
Power source	AC Line	AC Line	AC Line
Electrical safety and EMC	Electrical Safety per IEC-60601. UL listed	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.

7. **Summary of Bench Testing Conducted**: IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility. MTF and DQE measurements were supplied by the panel manufacturer in accordance with the FDA guidance document. Risk Analysis was conducted in accordance with FDA guidance documents.

8. **Summary of Clinical Testing:** Clinical images were acquired and evaluated by a board certified radiologist who concluded the images from the new panel are as good as the images acquired with the predicate panel.

9. **Conclusion:** After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Viztek Inc that the Viztek ViZion Ultra is as safe and effective as the predicate device, have few technological differences, and has the same indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

April 3, 2014

Viztek LLC
% Daniel Kamm, P.E.
Principal Engineer
Kamm & Associates
8870 Ravello Court
NAPLES FL 34114

Re: K133139
Trade/Device Name: ViZion Ultra
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: February 27, 2014
Received: March 6, 2014

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K133139

Device Name
Vizion Ultra, Digital Flat Panel X-ray Detector System

Indications for Use *(Describe)*
ViZion Ultra is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion Ultra allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

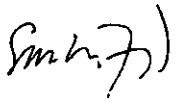
Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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