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

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

September 10, 2015

Re: K152279
Trade/Device Name: ViZion DR + Wireless
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: MQB
Dated: August 4, 2015
Received: August 12, 2015

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 Industry and Consumer Education 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 Industry and Consumer Education 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,

Robert Ochs, Ph.D.
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)*
K152279

Device Name
ViZion DR + Wireless

Indications for Use *(Describe)*
Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. ViZion DR + Wireless 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
510(k) Number K152279

Viztek, LLC.
2217 US HWY 70 East • Garner, NC 27529
Phone: 800.366.5343
Fax: 904.448.9936
Date Prepared: September 10, 2015
Contact: Bruce Ashby, Sales and Marketing Manager

1. **Identification of the Device:**
   Proprietary-Trade Name: ViZion DR + Wireless
   Classification Name: Stationary X-Ray System
   Product Code: MQB
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680

2. **Equivalent legally marketed device**: ViZion DR +, K123644, Viztek.
   Classification Name: Stationary X-Ray System
   Product Code: MQB,
   Common/Usual Name: Digital X-Ray Receptor Panel
   Device Class/Regulation Number: Class II per regulation 892.1680

3. **Indications for Use (intended use)** ViZion DR + Wireless 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 + Wireless allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.

4. **Description of the Device**: The ViZion DR + Wireless system represents the straightforward integration of a modified digital x-ray receptor panel and our previously cleared software. This is a MODIFICATION of our clearance K123644 wherein we have changed panel to a wireless version of the previously cleared panel/software combination. **Going wireless (with battery operation possible) are the ONLY modifications.**

   ViZion DR + Wireless is a Digital Radiography system, featuring an integrated flat panel digital detector (FPD). ViZion DR + Wireless 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 predicate is ViZion DR +, K123644. We do not supply the router, but any router meeting the IEEE 802.11 a/b/g/n specifications will work. With the advent of AED (automatic exposure detection) by the panel, integration with or connection to specific generators is no longer required. If the user decides NOT to use AED, wired synchronization with Sedecal Series SHF generators is known to work.

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 predicate.

6. Substantial Equivalence Chart

	Viztek ViZion + DR K123644	ViZion DR + Wireless
Intended Use:	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.	UNCHANGED
Configuration	This submission is for the Digital Panel and Software only, no generator or stand provided.	UNCHANGED
Digital Panel	iRay Technology (Shanghai) Ltd. For the 14" x 17" panel: Pixel size 150 µm 2288×2800 pixels (6.4 million pixels)	iRay Technology (Shanghai) Ltd. Mars1417V 14" x 17" panel: Pixel size 150 µm 2304×2800 (6.4 million pixels)
Software	Outputs a DICOM image.	SAME as K123644
DICOM 3	Yes	YES
A/D Conversion	14 bit	SAME
MTF	0.75 at 0.5 (1/mm)	0.75 at 0.5 (1/mm) (Essentially the same)
DQE	0.23 at 0.5 (1/mm)	0.27 at 0.5 (1/mm) (Essentially the same)
Scintillator	GOS scintillation screen.	UNCHANGED
Interface	Gigabit Ethernet	Wired : Gigabit Ethernet (1000BASE-T) Wireless : IEEE802.11a/b/g/n
Power source	AC Line	AC Line and/or Rechargeable Lithium Battery (3 hr run time)
Photo		
Electrical safety and EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	SAME, plus complies with FCC Part 15 Rules and Regulations

7. **Summary of Bench Testing Conducted:** IEC Standards were employed for: Electrical Safety and Electromagnetic Compatibility. We compared MTF and DQE measurements for the original and wireless versions of the panel and found them to be similar enough not to make a notable difference in acquired images. Risk Analysis and System operation verification tests were conducted in accordance with FDA guidance documents. Since no software modifications were required, confirmation testing was performed. Wireless communication testing was performed to verify wireless connectivity. We used a Cisco Linksys EA2700. The device was also found to comply with FCC requirements for wireless operation.

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 or better than 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 ViZion DR + Wireless is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.