



Food and Drug Administration  
10903 New Hampshire Avenue  
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Silver Spring, MD 20993-0002

Viztek LLC  
% Daniel Kamm  
Principal Engineer  
Kamm & Associates  
8870 Ravello Ct  
Naples, Florida 34114

May 20, 2016

Re: k160810  
Trade/Device Name: Vizion Dr + Wireless  
Regulation Number: 21 CFR 892.1680  
Regulation Name: Stationary X-Ray System  
Regulatory Class: Class II  
Product Code: MQB  
Dated: March 21, 2016  
Received: March 24, 2016

Dear Daniel 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,



FOR

Robert Ochs  
Director  
Division of Radiological Health  
Office of In Vitro Diagnostics  
and Radiological Health  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K16

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 K160810**

**Viztek, LLC.**

**2217 US HWY 70 East • Garner, NC 27529**

**Phone: 800.366.5343**

**Fax: 904.448.9936**

**Date Prepared: April 5, 2016**

**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 + Wireless, K152279, 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 K152279 wherein we have changed the panel scintillator to Cesium Iodide in addition to having the GOS scintillator available. Changing the scintillator is the only modification.

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 + Wireless, K152279. 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 device. Clinical images collected demonstrate equal or better image quality as compared to our predicate.

## 6. Substantial Equivalence Chart

	Viztek ViZion DR + Wireless K152279	ViZion DR + Wireless, CSI Scintillator
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 + Wireless allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.	UNCHANGED
Configuration	Digital Panel and Software only, no generator or stand provided.	UNCHANGED
Digital Panel	iRay Technology (Shanghai) Ltd. Mars1417V-PSI 14" x 17" panel: Pixel size 150 $\mu$ m 2304x2800 (6.45 million pixels)	iRay Technology (Shanghai) Ltd. Mars1417V-TSI 14" x 17" panel: Pixel size 150 $\mu$ m 2288x2784 (6.37 million pixels) NOT a meaningful DIFFERENCE.
Internal image storage	200 full size images	UNCHANGED
Image acquisition time	$\leq$ 5 Seconds	UNCHANGED
DICOM 3	Yes	YES
A/D Conversion	14 bit	UNCHANGED
Scintillator	DRZ-Plus Gd2O2S:Tb	CSI (Cesium Iodide)
MTF	0.75 at 0.5 (1/mm) (GOS)	0.83 at 0.5 (1/mm) (CSI) (Better)
DQE	0.27 at 0.5 (1/mm) (GOS)	0.55 at 0.5 (1/mm) (CSI) (Better)
Interface	Wired : Gigabit Ethernet (1000BASE-T) Wireless : IEEE802.11a/b/g/n	UNCHANGED
Power source	AC Line and/or Rechargeable Lithium Battery (4 hr run time)	UNCHANGED
Photo: Panel		

Photo: Charging Station		
Electrical safety and EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2. Complies with FCC Part 15 Rules and Regulations	SAME

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 modified 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, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.