Televere Systems LLC
% Robert Bakin
Regulatory Consultant
Technology and Business Law Advisors, LLC
1244 Capuchino
BURLINGAME, CA 94010

November 9, 2017

Re: K172124
Trade/Device Name: Televere Podiatry Digital Imaging System
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: October 10, 2017
Received: October 12, 2017

Dear Robert Bakin:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert Ochs

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)*

~~n/a~~ K172124

Device Name

Televere Podiatry Digital Imaging System

Indications for Use *(Describe)*

The Televere Podiatry Digital Imaging System is intended for digital image capture use in podiatry radiographic examinations, wherever conventional screen-film systems may be used. Not for mammography.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary:

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Prepared July 12, 2017

1. Identification of the Device:
Proprietary-Trade Name: Televere Podiatry Digital Imaging System
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 21 C.F.R. §892.1680

2. Equivalent legally marketed device: Televere Digital Imaging System (K170975).
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 21 C.F.R. §892.1680

3. Associated legally marketed devices: TigerView Professional (PACS Software) K061035. This is the software used with this device.
Classification Name: System, Image Processing, Radiological, Code LLZ
Common/Usual Name: Picture Archiving and Communications System
Device Class/Regulation Number: Class II per regulation 21 C.F.R. §892.2050

4. Indications for Use: The Televere Podiatry Digital Imaging System is intended for digital image capture use in podiatry radiographic examinations, wherever conventional screen-film systems may be used. Not for mammography. Not for fluoroscopy.

5. Description of the Device: The Televere Podiatry Digital Imaging System consists of a combination of digital imaging software, a flat panel display (FPD), a PC-based computer, and a power supply. The PC based computer, x-ray generator and the power-supply are necessary for a full imaging system but are not part of the subject device. The imaging software has previously been cleared by FDA (i.e., K061035, TigerView Professional) and is being used unchanged in the subject device. This previously cleared software provides basic image adjustment features - an image management system allowing the physician to acquire, display, edit (e.g., resize, adjust contrast, crop, etc.), review, store, print, and distribute medical images within a Picture Archiving and Communication System (PACS) environment. TigerView Professional runs on standard PC-compatible computers and is compatible with capture devices which attach to the computer using a Network Adaptor, USB port, PCI slot, parallel port, memory card, S-video port on a video capture card, or SCSI card.

The FPD component seeking clearance (Varex PaxScan 2530C) has not been previously cleared by FDA as an individual component. The FPD uses a large-area amorphous silicon sensor array with a gadolinium oxysulfide (GadOx) scintillator for displaying high quality images over a wide range of dose settings and is intended to be integrated into a complete X-ray system. This premarket notification seeks clearance for a combination finished device consisting of the combination of the previously cleared digital imaging software and the FPD component. The combination of the digital imaging software and the FPD does not affect the safety or efficacy of either component device alone, or in combination. A gigabit Ethernet port allows for tethered, non-wireless data transmission.

Integration-level requirements/restrictions: High-frequency X-ray generators that support AED enabled digital flat panel displays are compatible with the Televere Podiatry Digital Imaging System. Synchronization with the generator is achieved through the interface power unit, supplied. Alternately the panel has automatic exposure detection (AED). If this mode is used, the precautions listed in the panel user manual must be observed. The user should confirm that the generator/tubestand combination proposed employs only Electronic Product Radiation Control certified components. The user should use only trained service engineers during the integration process and fully test the system prior to use on patients.

6. **Safety and Effectiveness, Comparison to predicate device**. The results of clinical image inspection, bench, and laboratory test results demonstrate that the new device is as safe and effective as the predicate device. Clinical images highlight equal or better image quality as compared to the predicate.

7. **Substantial Equivalence Chart**

	Predicate Device	**Device Seeking Clearance**
Device Name	Televere Digital Imaging System K170975	Televere Podiatry Digital Imaging System
Flat Panel Device	XRpad™ 4343F-N	PaxScan™ 2530C
Intended Use	The Televere Digital Imaging System is intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used. Allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities. Not for mammography.	The Televere Podiatry Digital Imaging System is intended for digital image capture use in podiatry radiographic examinations, wherever conventional screen-film systems may be used. Not for mammography. Not for fluoroscopy.
Configuration	Digital Panel and Software only, no generator or stand provided	SAME
Digital Panel Pixels	4318 x 4320	1792 x 2176
Digital Panel Pitch	100µm	139µm
Internal Image Storage	1 GB DDR3, 4 GB SDHC card, image number depends on image size (e.g., for 10 mb image there would be room for 500 images).	none
Image Acquisition Time	< 5 seconds	1 second
DICOM 3	YES via software cleared in K061035	SAME
A/D Conversion	16 Bit	SAME
Scintillator	Gadolinium Oxysulfide (GadOx)	SAME
MTF	55% (1 cy/mm), 25% (2cy/mm), 5% (4	55% (1 cy/mm), 23% (2cy/mm), 5% (4

	cy/mm) for RQA5.	cy/mm) for RQA5.
DQE	40% (0 cy/mm), 30% (1 cy/mm), 10% (3 cy/mm) for RQA5.	31% (0 cy/mm), 22% (1 cy/mm), 7% (3 cy/mm) for RQA5.
Interface	Gigabit Ethernet Port	SAME
Panel Size	460 mm (w) × 460 mm (l) × 15 mm (h)	249 mm (w) x 302 mm (l) x 49 mm (h)
Power Source	External Power Supply 100-240 VAC	SAME
Electrical Safety & EMC	EC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: Collateral Standard Electromagnetic Compatibility Requirements and Tests IEC 60601-1-2 Edition 4.0 2014-02 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests	SAME

Substantial Equivalence Conclusion: The comparison table reveals there are no new technical issues of safety or effectiveness raised by substitution of the digitalx-ray panel. Professional evaluation of imaging samples were of excellent quality, high resolution, clinically acceptable and substantially equivalent to the predicate device.

8. Summary of Bench Testing Conducted: IEC Standards have been employed for: Electrical Safety and Electromagnetic Compatibility. The panel power supply is UL Listed. We compared MTF and DQE measurements for the original and modified scintillator versions of the panel and found them to be similar enough not to make a notable difference in acquired images. As compared to the predicate panel the MTF and DQE performance of the new panel is substantially equivalent. The digital panel manufacturer conducted performance testing according to the FDA guidance document for solid state digital x-ray panels. 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. Labeling was developed to comply with the FDA solid state panel guidance document.

9. Summary of Clinical Testing: Sample clinical images from the new device were also provided however they were not necessary to demonstrate substantial equivalence.

10. Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Televere that the Televere Podiatry Digital Imaging System is as safe and effective as the predicate device K170975, has few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device. The new and predicate devices provide values for MTF and DQE that are substantially equivalent.