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

April 20, 2018

Re: K180765
Trade/Device Name: Televere Podiatry X-Ray System HF
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: March 21, 2018
Received: March 23, 2018

Dear Mr. 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.

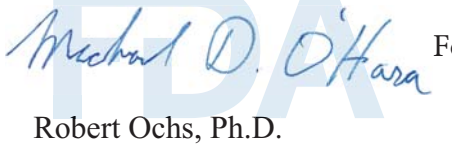
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



For

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 K180765

Device Name
Televere Podiatry X-Ray System HF

Indications for Use *(Describe)*
The Televere Podiatry X-Ray System HF is intended for use by qualified clinicians for the x-ray of hands and feet. Not for mammography. Not fluoroscopy.

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:

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1244 Capuchino Avenue,
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Phone: 571-215-3507
Prepared March 20, 2018

1. Identification of the Device:
Proprietary-Trade Name: Televere Podiatry X-Ray System HF
Classification Name: Stationary X-ray System
Product Code: KPR
Common/Usual Name: Stationary X-Ray System
Device Class/Regulation Number: Class II per regulation 21 C.F.R. §892.1680

2. Equivalent legally marketed device: Model HF 718BD X-Ray System (K160857), X-CEL X-Ray Corp.
Classification Name: Stationary X-ray System
Product Code: KPR
Common/Usual Name: Stationary X-Ray System
Device Class/Regulation Number: Class II per regulation 21 C.F.R. §892.1680

3. Associated legally marketed devices: TigerView Professional (PACS Software) K061035, Televere Systems, LLC. 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 X-Ray System HF is intended for use by qualified clinicians for the x-ray of hands and feet. Not for mammography. Not fluoroscopy.

5. Description of the Device: The Televere Podiatry X-Ray System HF consists of a combination of previously cleared Tigerview digital imaging software (K061035), a high frequency X-Ray generator (X-CEL MODEL HF 718BD, K160857), a PC-based computer and a power supply. Tigerview software provides an exposure control upgrade of the previously cleared HF x-ray generator by replacing the manual touchscreen of the Predicate Device (K160857) with the Tigerview computer software interface. Tigerview software provides basic image adjustment features as well as x-ray exposure control settings. An image adjustment system allows 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 software 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 previously cleared x-ray generator (K160857) contained minimal software functionalities and a manual x-ray exposure interface. The Proposed Device seeks to upgrade the manually entered x-ray exposure touchscreen of the Predicte Device with the Tigerview software computer interface. The combination of the digital imaging software and the x-ray generator does not affect the safety or efficacy of either component device alone, or in combination.

Integration-level requirements/restrictions:

The proposed device is compatible with flat panel detectors having AED functionality.

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	X-CEL X-Ray Model HF 718BD X-Ray System	Televere Podiatry X-Ray System HF
Indications for Use	The HF 718B X-Ray System is intended for use by qualified clinicians for the x-ray of hands and feet.	The Televere Podiatry X-Ray System HF is intended for use by qualified clinicians for the x-ray of hands and feet. Not for mammography. Not fluoroscopy.
Configuration	X-ray generator and Software only. No digital flat panel.	SAME
X-Ray Tube	Stationary anode Focal spot 1.0 mm NEMA Filtration 3.2 mmAl minimum X-ray tube current 10 mA fixed Kilovoltage to x-ray tube up to 90 kV Tube shielding 1 mm pb equivalent minimum	SAME
Waveform	High Frequency (HF)	SAME
Exposure Control	Manual Touchscreen	Tigerview Software
Power Requirements	105-130 volt AC @ 58-62Hz. Single phase. Less than 20 Amperes.	SAME
Exposure Factors	Exposure times from 50 to 500 mS Adjustable kilo-voltage from 50 to 90 kV No automatic exposure control or mAs settings	SAME

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Exposure Presets	14 - For repeatedly used techniques.	37 total (Ankle 10, Foot 9, Calcaneus 9, Other 9)
Exposure switch	Deadman	SAME
Performance accuracy	21 CFR 1020.31 compliant kVp accuracy at 50-90 kV = +/- 8% mA accuracy = +/- 1% Timer accuracy = +/- 5%. Reproducibility = 0.002cv Leakage Radiation = 34mR	SAME
X-ray Beam Quality Metrics	"kVp " "HVL " "mR " 50 1.71 6.38 60 2.40 8.37 70 2.69 14.49 85 3.05 19.95 90 3.31 22.87	SAME
Electrical Safety & EMC	Electrical Safety per IEC 60601-1 and EMC per IEC 60601-1-2.	SAME

7. Bench Testing Conducted:

- 21 CFR 1020.30 Diagnostic x-ray systems and their major components.
- 21 CFR 1020.31 Radiographic equipment
- 60601-1 3rd Edition Medical electrical equipment - Part 1: General requirements for safety
- 60601-1-2 3rd Edition Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
- 60601-1-6 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral Standard: Usability
- 62304:2006 Medical device software – Software life cycle processes
- 60601-2-54:2009 – Ed.1.0 Medical electrical equipment – Part 2-54: Particular requirements for the basic safety and essential performance of X-ray equipment for radiography and radioscopy
- 60601-3:2008-Ed. 2.0 Medical electrical equipment – Part 1-3: General requirements for basic safety and essential performance – Collateral Standard: Radiation protection in diagnostic X-ray equipment
- EC TR 60878 Graphical symbols for electrical equipment in medical practice
- EN ISO 14971 Application of risk management to medical devices
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied.

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

9. Conclusion: After analyzing bench, clinical image, and external laboratory testing to applicable standards, it is the conclusion of Televere that the Televere Podiatry X-Ray System HF 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.

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