June 20, 2018

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

Re: K181358
Trade/Device Name: Televere Digital Dental Imaging System
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: Class II
Product Code: MUH
Dated: May 20, 2018
Received: May 22, 2018

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 A. 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)*
K181358

Device Name

Televere Digital Dental Imaging System

Indications for Use *(Describe)*

The Televere Digital Dental Imaging System is intended for radiographic examination by a dental professional to assist in the diagnosing of diseases of the teeth, jaw and oral structures.. Not for mammography. Not for 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.

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

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TELEVERE SYSTEMS ACQUIRE STORE VIEW SHARE

510(k) Summary:

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Prepared May 20, 2018

1. Identification of the Device:
Proprietary-Trade Name: Televere Digital Dental Imaging System
Classification Name: Extraoral Source X-ray System
Product Code: MUH
Common/Usual Name: Intraoral Digital X-Ray Sensor
Device Class/Regulation Number: Class II per regulation 21 C.F.R. §872.1800

2. Equivalent legally marketed device: I View and Imagen Sensor (K162619).
Classification Name: Extraoral Source X-ray System
Product Code: MUH
Common/Usual Name: Intraoral Digital X-Ray Sensor
Device Class/Regulation Number: Class II per regulation 21 C.F.R. §872.1800

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 Digital Dental Imaging System is used for a radiographic examination by a dental professional to assist in the diagnosing of disease of the teeth, jaw and oral structures. Not for mammography. Not for fluoroscopy.

5. Device Description: The Televere Digital Dental Imaging System is an extraoral digital x-ray system comprised of two previously cleared individual components: (1) an intraoral detector component (K162619) which connects to a PC via a USB port and (2) and image management software package (i.e., Tigerview Professional, K061035). The device detector comes in two sizes: 600mm^2 (Hamamatsu CMOS area image sensor, S11684-12) and 884mm^2 (Hamamatsu CMOS area image sensor, S116845-12). X-ray generators that can integrate with the Televere Digital Dental Imaging System are wall-mounted x-ray generators (both AC and DC) with a tube current between 1 and 15mA inclusive, and with a tube voltage between 50 and 100kV inclusive, with built in controls to set exposure parameters. Generators allow variable mA/kV to be selected, all will control the exposure time. The device and software cannot act as an x-ray generator controller. All control of x-ray generation is done by controls built into the generator itself. There is no connection between the device and the x-ray generator. The device is an x-ray receiver and does not control the generator.

The previously cleared Tigerview™ Professional software (K061035) provides basic image adjustment features. 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™ 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. NOTE: The Tigerview ™ Professional software incorporated into the Televere Digital Dental Imaging system is unchanged from the Predicate software (i.e., K061035)

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	**Proposed Device**
Device Name	I-View and Imagen Sensor K162619	Televere Digital Dental Imaging System
CMOS Sensor	Hamamatsu, S11684/5-12	SAME
Intended Use	The Televere Digital Dental Imaging System is used for a radiographic examination by a dental professional to assist in the diagnosing of disease of the teeth, jaw and oral structures. Not for mammography. Not for fluoroscopy.	SAME
Configuration	CMOS sensor and imaging software only. No generator or stand provided.	SAME
Digital Panel Pixels	1000 x 1056 (S11684-12) 1300 x 1700 (S11685-12)	SAME
Software	Deep-View™	TIgerview Professional™, K061035
Scintillator	Cesium Iodide (CsI)	SAME
Interface	USB 2.0	SAME
Power Source	External Power Supply 100-240 VAC	SAME
Standards	IEC 60601-1 IEC 60601-1-2 IEC 62220-1--1:2015 ANSI 60529-2004 IEC 60601-2-65:2012	SAME

Substantial Equivalence Conclusion: The comparison table reveals there are no new technical issues of safety or effectiveness raised by substitution of the imaging software component. 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. The CMOS area image sensor 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 Digital Dental Imaging System is as safe and effective as the predicate device K162619, has few technological differences, and has no new indication(s) for use, thus rendering it substantially equivalent to the predicate device.