LiverMoreTech, Inc.
℅ Mr. Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
NAPLES FL 34114

February 14, 2020

Re: K193644
Trade/Device Name: E-COM DR-2000 DR
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: Class II
Product Code: MQB
Dated: December 24, 2019
Received: December 30, 2019

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for

devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193644

Device Name
E-COM DR-2000 DR

Indications for Use *(Describe)*
Intended for use in generating radiographic images of human anatomy. This device is intended to replace film/screen systems in all general purpose diagnostic procedures. This device is not intended for mammography applications. This device is intended for use by qualified medical personnel and is contraindicated when, in the judgment of the physician, procedures would be contrary to the best interest of the patient.

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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Exhibit 5 510(k) Summary K193644

LiverMoreTech, Inc.
801 North Jupiter Rd, Suite 200,
Plano, TX 75074, USA
• TEL: 214-257-0113
• FAX: 214-257-0116

Date Prepared: January 22, 2020

Contact: Jay Kim, Development Manager

1. **Identification of the Device:**
   Trade/Device Name: E-COM DR-2000 DR
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: II
   Product Code: MQB.

2. **Predicate device: K130883**
   Trade/Device Name: Sedecal Digital Radiographic Upgrade Model SDRU-T
   Manufacturer: Sedecal SA
   Regulation Number: 21 CFR 892.1680
   Regulation Name: Stationary X-ray System
   Regulatory Class: II
   Product Code: MQB.

3. **Description of the Device: This is a Windows 10 based software to be used in conjunction with an FDA cleared digital x-ray receptor panel. It can be used to upgrade film-based systems. This upgrade allows to acquire digital medical diagnostic X-ray images and transfer the images to hardcopy, softcopy, and archive devices on the same network. Some functions allowed with the E-COM DR-2000 DR software:**
   a. **Add new patients to the system, enter information about the patient and physician that will be associated with the digital radiographic images.**
   b. **Edit existing patient information.**
   c. **Emergency registration and edit Emergency settings.**
   d. **Pick from a selection of procedures, which defines the series of images to be taken.**
   e. **Adjust technique settings before capturing the X-ray image.**
   f. **Preview the image, accept or reject the image entering comments or rejection reasons to the image. Accepted images will be sent to the selected output destinations.**
   g. **Save an incomplete procedure, for which the rest of the exposures will be made at a later time.**
   h. **Close a procedure when all images have been captured.**
   i. **Review History images, resend and reprint images.**
   j. **Re-exam a completed patient.**
   k. **Protect patient records from being deleted by the system.**
   l. **Delete an examined Study with all images being captured.**
   m. **Edit user accounts.**
   n. **Check statistical information.**
   o. **Image QC.**
   p. **Image stitching.**

4. **Indications for Use: Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities.**

5. **Technological Characteristics: This device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device. Specifications are for all intents and purposes identical. This submission represents the combination of two cleared devices: Software, and Digital X-Ray panel(s). The software is an updated version of the software supplied in the predicate device K130883 and is now compatible with more FDA cleared digital panels.**

6. **Comparison Table**

Characteristic	Predicate Device K130883 Sedecal Digital Radiographic Upgrade Model SDRU-T	Proposed New Device E-COM DR-2000 DR
Indications for Use	Sedecal Digital Radiographic Upgrade Model SDRU-T is intended for digital image capture use in general radiographic examinations, wherever conventional screenfilm systems may be used, excluding fluoroscopy. angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine. abdomen, pelvis. and extremities.	Intended for digital image capture use in general radiographic examinations, wherever conventional screen-film systems may be used, excluding fluoroscopy, angiography and mammography. The kit allows imaging of the skull, chest, shoulders, spine, abdomen, pelvis, and extremities. (Identical)
Platform	Windows 7, 8, and 10	Windows 10. Older Windows versions are no longer supported by Microsoft
Compatible Digital X-Ray Receptor Panel(s)	Toshiba FDX4343R or FDX3543RP	Toshiba FDX4343R Detector Toshiba FDX3543RP Detector Toshiba FDX3543RPW Detector Toshiba FDX2530RPW Detector Toshiba FDX4343RPW Detector Thales Pixium RAD 4143 Detector Thales Pixium RAD 4343 Detector Thales Pixium RAD 3543 Detector Thales Pixium RAD 3543EZ Detector Thales Pixium RAD 2430EZ Detector Thales Pixium RAD 3543DR Detector Varian PaxScan 4336R Detector Varian PaxScan 4343R Detector Varian PaxScan 4336X Detector Varian PaxScan 4336W Detector
Compatible Generator(s)	Sedecal	Sedecal, CPI, Siemens, Del.
DICOM 3 Compatibility	YES	YES

Panel Clearance Table

Panel ID	FDA Clearance
Toshiba FDX4343R Detector	**K130883**
Toshiba FDX3543RP Detector	**K130883**
Toshiba FDX3543RPW Detector	**K171353**
Toshiba FDX2530RPW Detector	**K162687**
Toshiba FDX4343RPW Detector	**K162687**
Thales Pixium RAD 4143 Detector	**K133139**
Thales Pixium RAD 4343 Detector	**K133139**
Thales Pixium RAD 3543 Detector	**K141440**
Thales Pixium RAD 3543EZ Detector	**K141440**
Thales Pixium RAD 2430EZ Detector	**K141440**
Thales Pixium RAD 3543DR Detector	**K191813**
Varian PaxScan 4336R Detector	**K172007**
Varian PaxScan 4343R Detector	**K172007**
Varian PaxScan 4336X Detector	**K172007**
Varian PaxScan 4336W Detector	**K172007**

7. **Bench/Performance Testing:** The results of bench testing (software validation and risk analysis for a moderate level of concern device) shows that this new device poses no new issues of safety or effectiveness, has essentially the same technological characteristics as the predicate, and is therefore substantially equivalent to the predicate device. Software and labeling was developed in accordance with the following FDA guidance documents*: Guidance for Industry and FDA Staff Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices; Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices; Guidance for Industry Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software, and Content of Premarket Submissions for Management of Cybersecurity in Medical Devices, Guidance for Industry and Food and Drug Administration Staff.*
   Risk management was conducted in accordance with IEC 14971, Application of Risk Management to Medical Devices. Pediatric use precautions have been added as a supplement to the User Manual.

8. **Clinical Testing: Not required for a showing of substantial equivalence.**

9. **Conclusion: Based on comparison to the 510(k) summary of the predicate device, its technical characteristics, the indications for use, and the near identical characteristics of the two products, we conclude that the E-COM DR-2000 DR is substantially equivalent to the named predicate device.**