DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 25, 2016

Koven Technology, Inc.
Heather Bell
President
12125 Woodcrest Executive Dr.
Suite 320
St Louis, Missouri 63141

Re: K153762
Trade/Device Name: Smartdop XT6
Regulation Number: 21 CFR 870.2880
Regulation Name: Ultrasonic Transducer
Regulatory Class: Class II
Product Code: JOP
Dated: April 22, 2016
Received: April 27, 2016

Dear Heather Bell:

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.

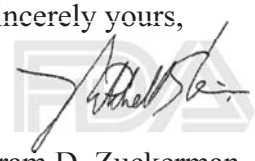
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*

K153762

Device Name
Smartdop XT6

Indications for Use *(Describe)*

The Smartdop XT6 is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe-brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs, photoplethysmography (PPG) and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link6 software that includes capabilities to print waveforms and export to into the facility's electronic health records.

It is not intended to be used in fetal applications or used inside the sterile field. It is intended to be used by licensed healthcare practitioners on adults and pediatrics only.

Diagnostic Ultrasound Indications documents follow this page.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: BT5M05S8A

Transducer: 5 MHz 510k#131623 Smartdop XT

Intended Use: The Smartdop XT6 is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe-brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs, photoplethysmography (PPG) and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link6 software that includes capabilities to print waveforms and export to into the facility's electronic health records. It is not intended to be used in fetal applications or used inside the sterile field. It is intended to be used by license healthcare practitioners on adults and pediatrics only.

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doooler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-ske!eta! **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Cardiac Adult							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				P			
	Other (Specify)							

N= new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Halt'monic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

K153762

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: BT8M05S8A

Transducer: 8 MHz 510k#131623 Smartdop XT

Intended Use: The Smartdop XT6 is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe-brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs, photoplethysmography (PPG) and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link6 software that includes capabilities to print waveforms and export to into the facility's electronic health records. It is not intended to be used in fetal applications or used inside the sterile field. It is intended to be used by license healthcare practitioners on adults and pediatrics only.

Clinical Application		Mode of Operation						
General (Track 1 Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				P			
	Other (Specify)							

N = new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Harmonic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

Appendix G: Example Diagnostic Ultrasound Indications For Use Format

System: Smartdop XT6

Transducer: Device

Intended Use: The Smartdop XT6 is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe-brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs, photoplethysmography (PPG) and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link6 software that includes capabilities to print waveforms and export to into the facility's electronic health records. It is not intended to be used in fetal applications or used inside the sterile field. It is intended to be used by license healthcare practitioners on adults and pediatrics only.

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks 1 & 3)	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other* (Specify)
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal							
	Abdominal							
	Intra-operative (Specify)							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric							
	Small Organ (Specify)							
	Neonatal Cephalic							
	Adult Cephalic							
	Trans-rectal							
	Trans-vaginal							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skeletal **(Conventional)**							
	Musculo-skeletal **(Superficial)**							
	Intravascular							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph. (Cardiac)							
	Intra-cardiac							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel				N			
	Other (Specify)							

N= new indication; P = previously cleared by FDA; E = added under this appendix

* Examples of other modes of operation may include: A-mode, Amplitude Doppler, 3-D Imaging, Halt'monic Imaging, Tissue Motion Doppler, and Color Velocity Imaging

510(k) Summary, Section 5

Date of Preparation: December 28, 2015

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with 21 CFR Sec. 807.92. A 510(k) Statement is not provided.

Company making this submission:

Submitter / Owner	
Company Name:	**Koven Technology, Inc.**
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Fax:	**314-542-6020**
Responsible Person:	**Ms. Heather Bell, President**
E-Mail Address:	**koven@koven.com**

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Telephone:	314.542.2101
Fax:	314.542.6020
E-mail Address:	koven@koven.com

Device Name:

Trade/Proprietary Name:	**Smartdop XT6 with Smart-XT-Link6**
Common/Usual Name:	**Ultrasonic transducer**
Regulation Number:	**870.2880**
Product Code:	**JOP**

Substantial Equivalency:

The Smartdop XT6 is substantially equivalent to other devices intended for use in the noninvasive evaluation of peripheral vascular pathology now in market. The predicate device is the Smartdop XT manufactured by Hadeco Inc., Kawasaki, Japan, with S.E number of K131623.

Device description:

The Smartdop XT6 with Smart-XT-Link6 is designed to provide both qualitative and quantitative information. The qualitative information mainly includes visual display of waveform's shapes, including qualitative analysis of Pulse Volume Recordings (PVR),

Photoplethysmography (PPG) and Doppler waveforms. The quantitative information is focused primarily on aiding the examiners in obtaining systolic segmental blood pressures, including the ABI (ankle-brachial index) and TBI (toe-brachial index). Additional quantitative measurements relate to the Doppler blood flow velocity waveforms. Foot skin temperature readings are done with optional temperature probe and can be displayed in either Fahrenheit or Celsius. All tests controlled and stored by computer with Smart-XT–Link6 software for Windows OS with capabilities to print waveform data and export to electronic health record management systems.

Clinical Applications:

The Smartdop XT6 with Smart-XT-Link6 clinical applications is:

ABI and TBI studies	Bi-directional Doppler lower extremity studies
Blood pressure segmental studies	PPG toe pressure & venous reflux studies
PVR arterial studies	Foot temperature readings

Principles:

Doppler blood velocity measurement

While performing Doppler waveform tests using Doppler Arterial Testing, blood flow velocity is detected through ultrasound which is transmitted from probe to patient body and is reflected by the blood (hemocyte, etc.).

The unit amplifies the high frequency oscillation output and then supplies it to the transmitter transducer. It is converted to ultrasound by the transducer and the ultrasound is transmitted to external objects. Then ultrasound moves straight through biophysical objects, and is reflected by the moving object (blood flow, fetal heartbeat, etc.).

The reflected ultrasound is received by the receiving transducer and is converted into electric signals again. The converted signals are amplified and then detected. After removing unnecessary noise from the signals and improving S/N ratio at the filter circuit, the Doppler shift signals are amplified and are converted to audible sounds through the speaker. Simultaneously, the Doppler shift signals are applied to the CPU and converted to blood flow velocity waveform signals which can be displayed.

Doppler blood pressure measurement

While taking blood pressures using Doppler Arterial Testing, the blood pressure cuff is wrapped where the blood pressure is taken and the probe is put on the arm/leg artery by the operator.

Before the inflation, the peak amplitudes of the blood flow signals should be stable. As the cuff pressure goes up by activating the inflation pump, the blood vessel is being compressed and the peak amplitudes become lower. The CPU finds the point where the peak amplitudes are below the threshold and waits until the cuff pressure is inflated an estimated 20 mmHg above the point. Then, the CPU deactivates the inflation pump and lets the cuff pressure go down at a moderate rate until the first blood flow signal that exceeds the threshold is detected.

The cuff pressure at the first signal is the systolic pressure. After confirming a return of the rhythmical blood flow signals, the CPU opens the air valve to dump the cuff pressure and the converted systolic pressure waveform signals can be displayed.

Oscillometry (Automatic)

While taking blood pressures on Automatic Arterial Testing screen and deflating cuff for arm or leg after the inflation, the unit detects oscillation of the blood vessel synchronizing with each heart beat and determines the systolic pressure based on oscillometry algorithm.

Photoplethysmography

While taking toe pressures with the PPG probe as well as performing PPG venous reflux study, the unit senses the reflection of light from the hemoglobin in the red blood cells in surface vessels using infrared light within the probe.

Pneumoplethysmography (PVR)

While performing PV waveform tests for toes and legs on either Automatic or Doppler Arterial Testing, the unit assesses changes in blood volume in the tissues beneath an inflated cuff. Alterations in pressure are transmitted to a pressure transducer that records the volume changes through the cardiac cycle to produce a waveform.

Probes and Cuffs:

- Cuffs: Up to 6: Refer the following cuff size as example:

VC-10H: VC-12H:	For brachial, above knees, below knees ankles and high thighs
UDC-1.9:	For great toes
VC-7.5H:	For transmetatarsal

- Probes:

	Model name	Freq.	Probe power (In situ)
Doppler probe (8MHz):	BT8M05S8C (A)	8MHz	390 mW/cm^2 or less
Doppler probe (5MHz):	BT5M05S8C (A)	5MHz	
Photoplethysmography:	PPG		
Temperature probe:	TP-01		

Indication for Use Statement:

The Smartdop XT6 is intended for use in the non-invasive evaluation of peripheral vascular pathology in patients. It detects systolic pressures for ankle-brachial index (ABI), toe- brachial index (TBI), and arterial and venous blood flow in extremities. Measurements are provided utilizing cuffs, photoplethysmography (PPG) and/or Doppler probe. The optional foot temperature probe provides skin temperature readings on the foot. Collected data is captured and stored with Smart-XT-Link6 software that includes capabilities to print waveforms and export to into the facility's electronic health records.

It is not intended to be used in fetal applications or used inside the sterile field. It is intended to be used by licensed healthcare practitioners only.

Testing:

The Smartdop XT6 was designed to meet the following Standards and Guidance:

- IEC 60601-1 Medical electrical equipment 2007
- IEC 60601-1-2 Medical electrical equipment – Part 1-2: Collateral Standard Electromagnetic compatibility (2007).
- IEC 60601-2-37 Medical electronic equipment – Part 2-37: Particular requirement for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment (2007-08).
- IEC 62304 Medical device software – Software life cycle processes (2006-05).
- ISO 14971, Medical devices – Application of risk management to medical devices (2007-10-01).
- ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers
- ANSI/AAMI/ISO 81060-1:2007 Non-invasive sphygmomanometers Part 1: Requirements and test methods for non-automated measurement type.

The Smartdop XT6 testing was completed with acceptance to the above Standards. The Smartdop XT6 device probes and cuff are previous FDA released devices, with complete and accepted testing and validation.

The Smartdop XT6 system have been subjected to Bio-Compatibility, Electrical Safety, Mechanical Safety, Acoustic Output, EMC emissions and immunity, and performance testing by certified laboratories. Internally the Smartdop XT6 is subjected to unit testing, verification, performance testing, and validation to ensure that the device(s) meet all of their functional specifications listed in the Device Master Record.

The Smartdop XT6 labeling includes instructions for safe and effective use, warning, cautions and guidance for use.

Literature Review:

A review of the literature pertaining to the safety of the Smartdop XT6 non-invasive peripheral vascular diagnostic systems has been conducted and appropriate safeguards have been incorporated in the design of the Smartdop XT6 non-invasive peripheral vascular diagnostic systems.

Differences between Smartdop XT6 and Predicate:

The method of device construction and technology are the same. The only difference between the Smartdop XT6 and the Smartdop XT are the number of pressure ports. Smartdop XT6 has 6 pressure ports and the Smartdop XT has 14 pressure ports.

Conclusions:

The conclusion drawn from these tests is that the Smartdop XT6 non-invasive peripheral vascular diagnostic system is equivalent in safety and efficacy to the predicate device.