January 5, 2021

Koven Technology, Inc.
% Harvey Knauss
Consultant
Delphi Consulting Group
11874 South Evelyn Circle
Houston, Texas 77071

Re: K201114
Trade/Device Name: Bidop 7
Regulation Number: 21 CFR 870.2100
Regulation Name: Cardiovascular Blood Flowmeter
Regulatory Class: Class II
Product Code: DPW
Dated: April 21, 2020
Received: April 27, 2020

Dear Harvey Knauss:

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 LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K201114

Device Name

Bidop 7

Indications for Use *(Describe)*

The Bidop 7 is intended for the detection of arterial and venous blood flow in the extremities as well as fetal heart sounds. The Bidop 7 displays bi-directional velocity waveforms, numerical data and fetal heart rate with heartbeat indicator. The Bidop 7 probe selection is 2, 5, 8, and 10 MHz.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

VASCULAR INSTRUMENTS
KOVEN
TECHNOLOGY INCORPORATED
Your Vascular Healthcare Partner

K201114 510(k) Summary

April 21, 2020

This Bidop 7 510(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.**
Address:	**477 N. Lindbergh Blvd, Ste. 220**
City, State and ZIP:	**St. Louis, MO 63141**
Telephone:	**314-542-2101**
Fax:	**314-542-6020**
Responsible Person:	**Ms. Heather Bell, President**
E-Mail Address:	**koven@koven.com**

Application Consultant	
Name:	Mr. J. Harvey Knauss
Address:	11874 South Evelyn Circle
City, State and ZIP:	Houston, TX 77071
Telephone:	832-675-9281
Fax:	713-723-0786
E-mail Address:	harvey.knauss@gmail.com

Device:

Trade/Proprietary Name:	**Bidop 7**
Common/Usual Name:	**Ultrasonic transducer**
Classification Name:	**Blood Flow meter, Cardiovascular**
Regulation Number:	**870.2100**
Product Code:	**DPW**
Predicate Device Name	**Smartdop 45**
"K" Number	**K050601**

Substantial Equivalency:

The Bidop 7 is substantially equivalent to other devices intended for use in the non-invasive evaluation of peripheral vascular pathology now in market. The predicate device is the Smartdop 45 with 510(k) number of K050601.

Device description:

The Bidop 7 is designed to provide both qualitative and quantitative information. The qualitative information mainly includes color visual display of waveform's shapes, including qualitative analysis of 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.

Clinical Applications:

The Bidop 7 clinical applications are:

ABI and TBI studies	Bi-directional Doppler extremity studies
Blood pressure segmental studies	PPG toe pressure & venous reflux studies

Principles:

Doppler blood velocity measurement and sounds for systolic pressures:

While obtaining Doppler arterial waveforms, blood flow velocity is detected through the ultrasound which is transmitted from probe to patient body and is reflected by the blood (hemolytic, 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. The ultrasound moves straight through biophysical object 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 a speaker.
Simultaneously, the Doppler shift signals are applied to the CPU and converted to blood flow velocity waveform signals which can be displayed.

Photoplethysmography:

While taking toe pressures and/or waveforms with PPG probe as well as performing PPG venous reflex study, the unit senses the reflection of light from the hemoglobin of the red blood cells in surface vessels by utilizing infrared light with the probe.

Probes:

Model name		Freq.	Probe power (In situ)
Doppler probe:	ST8M05S8C	8MHz	720 mW/cm^2 or less
Doppler probe	ST5M05S8C	5MHz	720 mW/cm^2 or less
Doppler probe	ST10M5S8C	10MHz	720 mW/cm^2 or less
Doppler probe	ST2M05S8C	2MHz	94 mW/cm^2 or less
PPG probe:	PG-30		

Indication for Use Statement:

The Bidop 7 is intended for the detection of arterial and venous blood flow in the extremities as well as fetal heart sounds. The Bidop 7 displays bi-directional velocity waveforms, numerical data and fetal heart rate with heartbeat indicator. The Bidop 7 probe selection is 2, 5, 8, and 10 MHz.

Testing:

The Bidop 7 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).
- FDA - Marketing Clearance of Diagnostic Ultrasound Systems and Transducers.
- FDA - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices.

Differences between Bidop 7 and Predicate:

The general method of device construction and technology are identical. The Smartdop 45 has an integrated printer, the Bidop 7 does not.

Literature Review:

A review of the literature pertaining to the safety of the Bidop 7 range of non-invasive peripheral vascular diagnostic systems has been conducted and appropriate safeguards have been incorporated in the of the Bidop 7 of non invasive peripheral vascular diagnostic devices.

Conclusions:

The conclusion drawn from these tests is that the Bidop 7 non-invasive peripheral vascular diagnostic system is equivalent in safety and efficacy to the predicate device. Therefore, the Bidop 7 is substantially equivalent to the predicate.