DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
8050 Marshall Drive, Suite 205 Lenexa, KS 66214 (913)495-5100 Fax:(913)495-5115	2/2/2026-2/6/2026
	FEI NUMBER 1937397

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Heather S. Bell, President

FIRM NAME	STREET ADDRESS
Koven Technology, Inc.	477 N Lindbergh Blvd Ste 220
CITY, STATE, ZIP CODE, COUNTRY Saint Louis, MO 63141-7856	TYPE ESTABLISHMENT INSPECTED Manufacturer and Repackager/Relabeler

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

The significance of the design and development change to safety and regulatory requirements for the medical device and its intended use was not determined.

Specifically, Koven Technology failed to document design and development changes related to expanding the indications for use of the Bidop 3 (K954397) to include a fetal application.

Per Koven Technology procedure, 1-SOP-014, Design Control, all design changes must be identified, documented, where appropriate validated, reviewed and approved before the changes may be implemented. Records are maintained.

Per Koven Technology procedure 2-SOP-010, Device Registration, Submission and Notification, once a device or process is changed, (b) (4)
(b) (4)

Koven Technology is the 510(k) K954397 holder and distributor of the Bidop 3. Per Koven's website, the Bidop 3 fetal Doppler is a hand-held ultrasound Doppler with fetal heart LCD display. It is used to determine fetal heart rate and sounds. The Bidop 3 operations manual notes the indications for use include detection of fetal heart sounds.

Koven's original (510(k) K954397 filing) intended use did not include fetal use. Koven Technology's

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	Edward E Lockwood, Investigator X Edward E Lockwood Investigator Signed By: Edward E. Lockwood - S Date Signed: 02-06-2026 15:09:11	2/6/2026

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510(k) Notification--Reply to Deficiency Letter, dated February 19, 1996, to the FDA from Koven Technology documents the device is not recommended for fetal use.

Koven has no documentation of:

A. Date change was approved

B. Date distribution was initiated for the BiDop 3 as a Fetal Doppler.

C. Approval/review of design change documentation, including:

1. Specific modifications made to the device (hardware, software, or performance specifications) to support fetal use
2. Validation data demonstrating the device's safety and effectiveness for fetal applications.

D. Demonstrating that the firm evaluated whether the change in indications for use (from non-fetal to fetal application) required a new 510(k) submission.

OBSERVATION 2

Records of the review, evaluation, and investigation for any complaints involving the possible failure of a device, labeling, or packaging to meet any of its specifications were not adequately maintained.

Specifically,

Per Koven Technology's Customer Complaint SOP, 4-SOP-050,

- A complaint is any written, electronic, or oral communication that alleges deficiencies, reliability, usability, safety, or performance or a medical device.

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- (b) (4)

Koven Technology receives calls and emails concerning medical devices issues. (b) (4)

(b) (4)

If the device can be returned for inspection, an RGA (returned goods authorization) is issued to the customer and the information is documented on a Service RGA form, including the code for the nature of the return.

From 1/1/2024 thru 12/31/2025 approximately (b) (4) RGA's were issued for device returns. I reviewed 29 completed RGA forms coded (b) (4) Thirteen (13) of the forms reviewed documented device failures affecting performance/reliability. For example:

RGA Number	Date	Device	Code	Failure/Inspection
10923	6/26/2024	Bidop 7	(b) (4)	The doppler memory has been cleared and when it is turned off and on, it comes up memory store #11 or memory store #1. The doppler should go straight to the LCD screen.
11061	9/18/2024	Bidop 3		No consistent waveform with toe pressure sensor
11211	1/8/2025	Bidop 3		Out of box failure
11509	6/27/2025	CRP-20H, cardiovascular probe		Not picking up vascular flow
11402	4/22/2025	Aneroid		Doesn't measure correctly on arms,

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		Sphygmomamanometer		ankles and feet.

Koven Technology did not consider these reports as complaints and did not initiate or complete a complaint form, per procedure.

OBSERVATION 3

Criteria for the evaluation and selection of suppliers were not adequately established.

Specifically,

Your firm does not have adequate criteria for the evaluation and selection of your approved supplier, Company A, based on their ability to provide product that meets requirements, the performance of the supplier, and the effect of the purchased product on the quality of the device, proportionate to the risk associated with the medical device.

A. Your firm holds 25 510(k) clearances (clearance dates ranging from July 28, 1989 to January 5, 2021) for devices designed and manufactured by Company A, a foreign manufacturer. When asked to review the change history for your 510(k) devices, your firm stated that it had not received any design change notifications from Company A for any of the medical devices. Your quality agreement with Company A requires notification of labeling changes.

During this inspection, the BiDop 3 Doppler (K954397, cleared March 29, 1996) was found to have indications for use that differ from the cleared 510(k). Specifically, the indications for use were changed from non-fetal to fetal application—a significant modification that affects the device's intended use and risk profile. Your firm does not have documentation of this change and could not identify when this change occurred. This undocumented change represents a failure by Company A to meet the change notification requirements established in your quality agreement.

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B. You have evaluated Company A as a (b) (4) supplier with highest impact to Koven quality and products. The quality agreement between your firm and Company A (Section 5.5, Labeling) requires Company A to notify your firm of labeling changes, including indications for use, and requires your firm to evaluate whether a regulatory notification is needed.

However, the agreement does not require notification of design changes beyond labeling, does not provide your firm access to Company A's design change logs or design history files, and lacks verification mechanisms to ensure Company A's compliance with change notification requirements. Your firm could not provide documented evidence how the scope of the quality agreement was determined to be adequate for devices where Company A controls all design and manufacturing activities.

C. Per procedure 1-SOP-020, (b) (4) supplier approval criteria includes requirements for a quality agreement, supplier quality master sheet (Form 1-SOP-020 F-2) and site assessment (Supplier Audit, form 7-SOP-025 F-1). There is no documentation that a site assessment (Supplier audit) has been accomplished for company A, a (b) (4) supplier. There is no documentation of the rationale for waiving this requirement.

OBSERVATION 4

In product realization planning your firm did not adequately determine, as appropriate, quality objectives and requirements for the product.

Specifically, Koven Technologies is a 510K holder and distributor of fetal dopplers.

I reviewed risk management analysis for two (2) of Koven Technology's fetal dopplers revealed inadequate hazard identification and risk analysis, as follows:

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A. Product ES-100V3 (aka Bidop 3 in US market), 510(k) K954397, approval date 3/29/1996. Risk management report dated 9/3/2025, report number (b) (4) I was advised by management this report included revisions for the Bidop 3 to include indication of use as a fetal heart rate doppler. This report contains no evaluation of risks to the fetus, despite the device's labeling for use to determine fetal heart rate and sounds.

B. Product Bidop 7, 510(k) K201114, approval date 1/5/2021. Risk management report dated 2/5/2020, document number (b) (4) This report contains no evaluation of risks to the fetus, despite the device's indication for use, displays bi-directional velocity waveforms, numerical data and fetal heart rate with heartbeat indicator.

The fetus is directly exposed to ultrasound energy and is the primary patient population for these devices. Failure to evaluate fetal-specific hazards (e.g., thermal effects, acoustic exposure, diagnostic accuracy affecting clinical decisions) represents inadequate risk analysis for the devices' intended use.

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

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X Edward E Lockwood
Investigator
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The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."