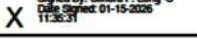


DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 1/13/2026-1/15/2026 FEI NUMBER 3015536408	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brooke D. Hanna, Director of Operations			
FIRM NAME MIDWAY MEDICAL		STREET ADDRESS 3004 Gill St	
CITY, STATE, ZIP CODE, COUNTRY Bloomington, IL 61704-2540		TYPE ESTABLISHMENT INSPECTED Specification Developer	
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.			
<i>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.</i>			
DURING AN INSPECTION OF YOUR FIRM I OBSERVED: OBSERVATION 1 Procedures for receiving, reviewing, and evaluating complaints by a formally designated unit have not been established. Specifically, your firm has not established written procedures for complaint handling to receive, review, and evaluate complaints. The firm, as a Specification Developer, distributed ■ units of a Class II device (K190975, Product Code JOW, Compressible Limb Sleeve), the Plexus SCD110 Sequential Compression Device Sleeve. The device is intended to be used preventatively to increase venous blood flow in patients at risk of deep vein thrombosis due to associated risk factors for thrombus formation during trauma, critical care, general medicine, general surgery, as well as neurological, orthopedic, urologic, and obstetric conditions and treatments.			
OBSERVATION 2 Procedures to ensure that all purchased or otherwise received product and services conform to specified requirements have not been established. Specifically, your firm has no established written procedures for purchase controls. Your firm, as the Specification Developer of a Class II medical device (K190975, Product Code JOW, Compressible Limb Sleeve), the Plexus SCD110 Sequential Compression Device Sleeve—a device intended for			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Clifford F Long, Investigator		DATE ISSUED 1/15/2026 Clifford F Long Investigator Signed By: Clifford F. Long-S Date Signed: 01-15-2026 11:35:31 

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 1/13/2026-1/15/2026 FEI NUMBER 3015536408	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brooke D. Hanna, Director of Operations			
FIRM NAME MIDWAY MEDICAL		STREET ADDRESS 3004 Gill St	
CITY, STATE, ZIP CODE, COUNTRY Bloomington, IL 61704-2540		TYPE ESTABLISHMENT INSPECTED Specification Developer	
preventative use to increase venous blood flow in patients at risk of deep vein thrombosis—had a contract manufacturer in 2019 perform design controls and manufacture units without established written procedures, conducting a supplier evaluation, or executing a supplier agreement.			
OBSERVATION 3 Written MDR procedures have not been developed and implemented. Specifically, your firm has been a Specification Developer of a Class II medical device since 2019 and not established written procedures for review complaints and determine whether events must be reported to the FDA.			
OBSERVATION 4 Procedures for corrective and preventive action have not been established. Specifically, your firm has been a Specification Developer of a Class II medical device since 2019 and not established written procedures for corrective and preventive action (CAPA).			
OBSERVATION 5 The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided. Specifically, your firm has not submitted any information to the Global Unique Device Identification Database for the Compressible Limb Sleeve, the Plexus SCD110 Sequential Compression Device Sleeve.			
SEE REVERSE OF THIS PAGE		EMPLOYEE(S) SIGNATURE Clifford F Long, Investigator Clifford F Long Investigator Signed By: Clifford F. Long-S Date Signed: 01-15-2026 11:36:31 	
		DATE ISSUED 1/15/2026	

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
DISTRICT ADDRESS AND PHONE NUMBER 550 W. Jackson Blvd., Suite 800 Chicago, IL 60661-4716 (312) 353-5863 Fax: (312) 596-4187		DATE(S) OF INSPECTION 1/13/2026-1/15/2026 FEI NUMBER 3015536408	
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Brooke D. Hanna, Director of Operations			
FIRM NAME MIDWAY MEDICAL		STREET ADDRESS 3004 Gill St	
CITY, STATE, ZIP CODE, COUNTRY Bloomington, IL 61704-2540		TYPE ESTABLISHMENT INSPECTED Specification Developer	
Annotations to Observations Observation 1: Promised to correct Observation 2: Promised to correct Observation 3: Promised to correct Observation 4: Promised to correct Observation 5: Promised to correct			
SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Clifford F Long, Investigator		DATE ISSUED 1/15/2026 Clifford F Long Investigator Signed By: Clifford F. Long -S Date Signed: 01-15-2026 11:36:31

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."