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	2/18/2026-2/23/2026* FEI NUMBER 1937980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ms. Jenise M. Sexton, Operations Manager

FIRM NAME	STREET ADDRESS
Essex Industries, Inc.	8007 Chivvis Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Affton, MO 63123-2333	Manufacturer

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 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, Essex Industries has not submitted required device information to the Global Unique Device Identification Database (GUDID) for the following commercially distributed medical devices:

Device	Device Name	Part Number(s)	510K Number
(b) (4)			

***DATES OF INSPECTION**
2/18/2026(Wed), 2/19/2026(Thu), 2/23/2026(Mon)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward E Lockwood, Investigator	X Edward E Lockwood Investigator Signed By: Edward E Lockwood - S Date Signed: 03-23-2026 11:37:43	2/23/2026

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	2/18/2026-2/23/2026* FEI NUMBER 1937980

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Ms. Jenise M. Sexton, Operations Manager

FIRM NAME	STREET ADDRESS
Essex Industries, Inc.	8007 Chivvis Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Affton, MO 63123-2333	Manufacturer

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Edward E Lockwood, Investigator	X Edward E Lockwood Investigator Signed By: Edward E. Lockwood - S Date Signed: 02-23-2026 11:37:43	2/23/2026