DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/16/2014 - 08/07/2014* FEI NUMBER 2210968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Rick Sedlatschek, Vice President, Quality & Regulatory Compliance

FIRM NAME	STREET ADDRESS
Ethicon, Inc.	P.O. Box 151, Route 22 West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerville, NJ 08876-0151	Medical Device 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

Not all complaints have been adequately reviewed and evaluated to determine whether an investigation is necessary.

Specifically, the following customer complaints representing events that are MDR reportable were not promptly investigated. The firm's written procedure titled "Franchise Procedure for Product Compliant Management" PR-0000118, Rev. 25 indicates that the determination of level of review related to complaint defect category and DHR for the product is inclusive of finished goods, in process or raw material review. The SOP further indicates that complaint investigation that requires additional investigation is determined via the "Further Investigation Determination Table" and is escalated to the NCR and/or CAPA. However, the following complaints representing malfunction of the device were generated as described in the firm's procedure but not further investigated to determine the root cause of the event.

For example:

a. Compliant File Report - Product Issue #(b) (4) was generated to address a device malfunction regarding the VICRYL Plus Polyglactin 910 Suture (product code: VCP316H) which was reported for suture breakage at the user facility during a Laparoscopic Oophorocystectomy procedure. No further investigation was conducted to determine the circumstances to cause the breakage.

b. Compliant File Report - Product Issue #(b) (4) was generated to address a malfunction regarding the VICRYL Plus Polyglactin 910 Suture (product code: VCP316H) which was reported of suture breakage at user facility during a Hydrosalpinx operation. No further investigation was conducted to determine the circumstances to cause the breakage.

OBSERVATION 2

Procedures for corrective and preventive action have not been adequately established.

Specifically, the firm's written procedure titled "Franchise Procedure for Post Market Surveliance" PR-0000385, Rev. 7

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles J. Chacko, Investigator	08/07/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax: (973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/16/2014 - 08/07/2014* FEI NUMBER 2210968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Rick Sedlatschek, Vice President, Quality & Regulatory Compliance

FIRM NAME	STREET ADDRESS
Ethicon, Inc.	P.O. Box 151, Route 22 West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerville, NJ 08876-0151	Medical Device Manufacturer

contains Post Market Surveillance (PMS) process reviews for weekly and monthly complaints and adverse events executed via tracking, trending and analysis of safety signals, and product quality indicators. The SOP further indicates that if it is determined that the trend investigation is a potential safety issue, the Product Risk Escalation (PRE) Process Owner is notified and the trend is escalated via the Franchise PRE process. If warranted, a CAPA may be issued to address the trend event. However, review of the firm's (b) (4) Ethicon Products (EP) Compliant Review Meeting (PMS Trend Investigation Form), dated 5/19/2014 revealed a consecutive increase in instances of suture breakage events since March 2012 to present. Analysis of the Vicryl and Vicryl plus Suture trend analysis revealed that the number of reported instances and the complaint rate related to suture breakage has been recurrently above the rate of (b) (4) ppm. A CAPA has not been opened in association with the results of the trend analysis.

For example:

a. The three highest Vicryl Polyglactin 910 Suture Events and Event Rates for suture breakage are for the following months of Nov 2012 (43 events, (b) (4) ppm), Apr 2013 (46 events, (b) (4) ppm), and Mar 2014 (33 events, (b) (4) ppm).

b. The three highest Vicryl Plus Polyglactin 910 Suture Events and Event Rates for suture breakage are for the following months of Mar 2012 (19 events, (b) (4) ppm), Jul 2012 (16 events, (b) (4) ppm), and Nov 2012 (15 events, (b) (4) ppm).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles J. Chacko, Investigator	08/07/2014

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Fax:(973) 331-4969 Industry Information: www.fda.gov/oc/industry	07/16/2014 - 08/07/2014* FEI NUMBER 2210968

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. Rick Sedlatschek, Vice President, Quality & Regulatory Compliance

FIRM NAME	STREET ADDRESS
Ethicon, Inc.	P.O. Box 151, Route 22 West
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerville, NJ 08876-0151	Medical Device Manufacturer

Observation Annotations

Observation 1: Promised to correct. Observation 2: Promised to Correct.

*** DATES OF INSPECTION:**
07/16/2014(Wed), 07/17/2014(Thu), 07/21/2014(Mon), 07/22/2014(Tue), 07/24/2014(Thu), 07/25/2014(Fri), 08/05/2014(Tue), 08/07/2014(Thu)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Charles J. Chacko, Investigator	08/07/2014