Class 2 Device Recall VentiClear

Date Initiated by Firm: May 31, 2018
Create Date: August 12, 2018
Recall Status: Open, Classified
Recall Number: Z-2791-2018
Recall Event ID: 80492
510(K) Number: K011812
Product Classification: Catheter, ventricular (containing antimicrobial or antimicrobial agents)
Product: VentiClear Ventricular Drainage Catheter Set, Cat. No. N-VVDC-01-ABRM

Product Usage:
The VentiClear Ventricular Drainage Catheter Set has been designed for obtaining access to a ventricular cavity of the brain for short-term use to externally drain fluid for the purpose of relieving elevated intracranial pressure or fluid volume.

Code Information:
Lot: 8639185

Recalling Firm:
Cook Inc.
750 N Daniels Way
Bloomington IN 47404-9120

For Additional Information:
Contact Cook Medical Customer Relations Department
600-457-4500

Manufacturer Reason for Recall:
This lot of VentiClear failed endotoxin testing. Potential adverse events include immune responses ranging from non-specific febrile reaction to life-threatening systemic inflammatory response syndrome (SIRS).

FDA Determined Cause:
Release of Material/Component prior to receiving test results

Action:
On May 31, 2018, the firm contacted the single customer (a distributor) who received the entirety of the affected lot, via email. The email alerted the customer that the lot failed endotoxin testing and instructed the customer to quarantine the lot immediately. The firm then conducted a teleconference with the distributor to further discuss interim controls for future lot release. The recalling firm requested return of the affected lot. The distributor returned the lot to the firm. The recalling firm stated that none of the product was distributed to end users.

Quantity in Commerce: 250
Distribution:
One distributor in Indiana; product was not further distributed to end users.

Total Product Life Cycle:
TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=165597 8/20/2018