FDA

Class 2 Device Recall VentriClear

See Related Information[22]

Date Initiated by Firm	May 31, 2018
Create Date	August 12, 2018
Recall Status[1]	*Open*[3], *Classified*
Recall Number	Z-2791-2018
Recall Event ID	80492[23]
510(K)Number	K011812[24]
Product Classification	Catheter, ventricular (containing antibiotic or antimicrobial agents)[25] - **Product Code** NHC[26]
Product	VentriClear Ventricular Drainage Catheter Set, Cat. No. N-VVDC-01-ABRM Product Usage: The VentriClear 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/ Manufacturer	Cook Inc. 750 N Daniels Way Bloomington IN 47404-9120
For Additional Information Contact	Cook Medical Customer Relations Department 800-457-4500
Manufacturer Reason for Recall	This lot of VentriClear 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 [2]	*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[27]

[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.