FDA

Class 2 Device Recall Temperature Sensor Catheter

See Related Information [22]

Date Initiated by Firm	July 11, 2018
Create Date	September 20, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-3208-2018
Recall Event ID	80747[23]
510(K)Number	K933400[24]
Product Classification	Catheter, urological[25] - **Product Code** KOD[26]
Product	P400 PREM U/M 16FR TMPSNS, Item Code P4P16TS
Code Information	1814906864
Recalling Firm/ Manufacturer	COVIDIEN LLC 15 Hampshire St Mansfield MA 02048-1113
For Additional Information Contact	Customer Advocacy 800-292-9332
Manufacturer Reason for Recall	The temperature sensor catheters may be defective in that they will show a lower body temperature measurement than the actual temperature of the patient.
FDA Determined Cause [2]	Nonconforming Material/Component
Action	On 7/11/18, an Urgent Medical Device Recall letter was distributed to customers. The letter instructed customers to do the following: 1. Please quarantine any unused product of the Covidien item codes and lot numbers listed above (see Attachment A to locate). 2. If you have distributed any of the affected Covidien catheters or kits, then please promptly forward a copy of this letter to those recipients. 3. All unused product of affected item codes and lot numbers must be returned. 4. Please return unused affected product as explained below. You must complete the Recalled Product Return Form (Attachment B) regardless of whether or not you have inventory of affected product.
Quantity in Commerce	27515 total
Distribution	The products were distributed to the following US states: CA, CO, FL, GA, IA, IL, IN, KY, LA, MA, MD, MO, NC, NJ, NY, OH, OR, PA, RI, SC, TN, TX, VA, and WA.
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. Learn more about medical device recalls[28].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.