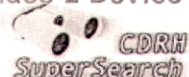




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Class 2 Device Recall Temperature Sensor Catheter

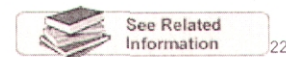


[6 510\(k\)|DeNovo⁸](#) | [Registration & Listing⁹](#) | [Adverse Events¹⁰](#) | [Recalls¹¹](#) | [PMA¹²](#) | [HDE¹³](#) | [Classification¹⁴](#) | [Standards¹⁵](#)
[CFR Title 21¹⁶](#) | [Radiation-Emitting Products¹⁷](#) | [X-Ray Assembler¹⁸](#) | [Medsun Reports¹⁹](#) | [CLIA²⁰](#) | [TPLC²¹](#)

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Class 2 Device Recall Temperature Sensor Catheter



| | |
|---|---|
| Date Initiated by Firm | July 11, 2018 |
| Create Date | September 20, 2018 |
| Recall Status¹ | 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 Cause² | 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.