Class 2 Device Recall Inteliport Medication Management System

Recall Date: March 08, 2016
Recall Status: Open
Recall Number: Z-1076-2016
Recall Event ID: 7300823
510(K) Number: K14147424
Product Classification: Infusion safety management software - Product Code PHC
Product: BD Inteliport Medication Management System Sensor

The system is indicated for use by healthcare professionals in a hospital or medical center setting with patients who are receiving manually administered bolus intravenous injections as part of their care to facilitate documentation of the medications.

Code Information: Catalog (Ref) # 516700 Lot numbers 5222723, 5251583 and 5253723.
Recalling Firm/Manufacturer: Becton Dickinson & Company
1 Becton Dr
Franklin Lakes NJ 07417-1815
For Additional Information Contact: Ms. Zuleika Sánchez
201-847-5216
Manufacturer Reason for Recall: The sterility of the product cannot be assured. This may result in increased risk of infection.
FDA Determined Cause: Under investigation by firm
Action: Becton Dickinson representatives notified their customers in person and a copy of the "Urgent Product Recall" letter and "Recall Response Form" dated 12/9/2015 was provided. The letter identified the reason for the recall; how to identify affected product; and the actions to be taken. The letter instructed customers to immediately review their inventory; complete the enclosed Recall Response Form and fax (1-201-847-4267) it to BD or email it to Becky_Saggau@bd.com even if you do not have any of the affected lot; and return all affected products with the completed Recall Response Form following instructions on the enclosed packing instruction. If customers have any questions or require assistance with the return of the recalled product and/or availability of replacement product, they were instructed to contact 1-201-847-4267 between 8AM and 5 PM ET Monday through Friday.
Quantity in Commerce: 250 units
Distribution: US Distribution to: California and Utah.