Class 2 Device Recall Intelliport Medication Management System

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Recall Date	March 08, 2016
Recall Status[1]	Open
Recall Number	Z-1076-2016
Recall Event ID	73008[23]
510(K)Number	K141474[24]
Product Classification	Infusion safety management software[25] - **Product Code** PHC[26]
Product	BD Intelliport 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 S¿nchez 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 [2]	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.