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Class 2 Device Recall Edwards Intravascular (IV) Administration Sets

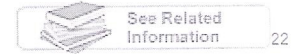


6 510(k) | De Novo⁸ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | HDE¹³ | Classification¹⁴ | Standards¹⁵ | CFR Title 21¹⁶ | Radiation-Emitting Products¹⁷ | X-Ray Assembler¹⁸ | Medsun Reports¹⁹ | CLIA²⁰ | TPLC²¹

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Class 2 Recall Edwards Intravascular (IV) Administration Sets



Date Posted December 17, 2015

Recall Status¹ Open

Recall Number Z-0446-2016

Recall Event ID 72690²³

Product Classification Transducer, Pressure, Catheter Tip²⁴ - Product Code DXO²⁵

Product Intravascular (IV) Administration Sets, Model No. 54IV12, 54IV22, 54IV32, MK2450, 54IV42, MK132, MK2156, MK2270, MK2292, MK2300, MK2374, MK2394, MK2508, MK2227

Code Information

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Recalling Firm/ Manufacturer	Edwards Lifesciences, LLC 1 Edwards Way Irvine, California 92614-5688
For Additional Information Contact	Mark Gayle 949-250-2500
Manufacturer Reason for Recall	Edward Lifesciences is recalling Intravascular (IV) Administration Sets due to the requirement of an additional FDA submission to support commercialization (clearance) of the devices.
FDA Determined Cause ²	OTHER/UNDETERMINED: Under Investigation by the firm
Action	An urgent product notification letter dated 11/13/15 was to customers to inform them that during an internal documentation review, the requirement of an additional FDA submission to support commercialization (clearance) of the devices was discovered. Customers are informed that the Edwards Lifesciences Intravascular (IV) Administration sets are temporarily unavailable for sale. Customers are informed that there is no increased risk to the patients' health or safety by using products in their current inventory and there is no impact to the IV sets included in pressure monitoring kits (with TruWave pressure transducer or VAMP system). Customers are informed that if they are in need of a substitute IV set, then to call customer service at (800) 424-3278. Customers instructed to respond to the customer response form by faxing it to (800) 422-9329.
Quantity in Commerce	147,350 units
Distribution	US
Total Product Life Cycle	<u>TPLC Device Report</u> ²⁶

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁷](#)

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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