Class 2 Recall Celsite Implantable Access Port System

See Related Information 23

Date Posted	August 13, 2015
Recall Status[1]	Open
Recall Number	Z-2382-2015
Recall Event ID	71666[24]
Premarket Notification 510(K) Number	K130576[25]
Product Classification	Port & Catheter, Implanted, Subcutaneous, Intravascular[26] - **Product Code** LJT[27]
Product	Celsite Implantable Access Port System, model ST301. The Celsite Implantable Access Port Systems (Celsite port systems) are implantable port and catheter systems that allow safe, repeated access to the patient's bloodstream. The port chamber and catheter design can be used for the administration of medication and fluids. The Celsite system consists of an access port with a silicone septum, which is connected to a catheter using a connection ring. The triangular shaped access port has a low profile nose, finger stops on the side of the housing, and a round base. Celsite access ports have suture holes or suture zones to secure placement during implantation.
Code Information	Lot number: 36896615
Recalling Firm/ Manufacturer	B. Braun Interventional Systems 3050 Ranchview Ln N Minneapolis, Minnesota 55447-1459
For Additional Information Contact	Paul O'Connell 763-553-1006
Manufacturer Reason for Recall	The manufacturer, B. Braun medical France, received endotoxin test results that are out of specification for the peelable sheath (A1537).
Action	An Urgent Medical Device Recall letter, dated 6/16/2015 was sent to the 2 consignees via express mail. The letter explained the issue and requested the hospital review their inventory for the affected model and lot. If any quantities of the lot remained in inventory, the product was to be returned to BIS. A BIS sales representative will personally visit each account and complete an inventory sheet. Customers with questions can contact Paul O-Connell, President at 1-847-274-0097.
Quantity in Commerce	11 units
Distribution	CA and NY only.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]

510(K) Database	510(K)s with Product Code = LJT and Original Applicant = B. BRAUN INTERVENTIONAL SYSTEMS INC.[30]