Class 2 Recall
Celsite Implantable Access Port System

Date Posted: August 13, 2015
Recall Status: Open
Recall Number: Z-2382-2015
Recall Event ID: 7166624
Premarket Notification 510(K) Number: K13057025
Product Classification: Port & Catheter, Implanted, Subcutaneous, Intravascular - Product Code LJT27

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
763-553-1005
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 Report28

510(K) Database: 510(K)s with Product Code = LJT and Original Applicant = B. BRAUN INTERVENTIONAL SYSTEMS INC.29

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5520

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=138664
8/31/2015