Class 2 Device Recall 9.6F Plastic Dignity MidSized CT port w/PreAttached Silicone Catheter

See Related Information[22]

Date Initiated by Firm	February 23, 2017
Date Posted	March 08, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1536-2017
Recall Event ID	76625[23]
510(K)Number	K132177[24]
Product Classification	Port & catheter, implanted, subcutaneous, intravascular[25] - **Product Code** LJT[26]
Product	9.6F Plastic Dignity Mid-Sized CT Port w/Pre-Attached Silicone Catheter The CT Power Injectable Implantable Infusion Ports are indicated for patient therapies requiring repeated access to the vascular system. The port system can be used for infusion of medications, I.V. fluids, parenteral nutrition solutions, blood products, and for the withdrawal of blood samples. When used with a power injectable needle, the Power Injectable Implantable Infusion Port device is indicated for power injection of contrast media
Code Information	MRCTI96801 Lot# MHWQ060 S2 , UDI# 884908031232
Recalling Firm/ Manufacturer	Medical Components, Inc dba MedComp 1499 Delp Dr *Harleysville* PA 19438-2936
For Additional Information Contact	Susan M. Smith 215-256-4201
Manufacturer Reason for Recall	The 9.6F port kits were packaged with the incorrect valved peelable introducer. The label states the kit contains a 10F valved peelable introducer. The kit is packaged with a 9F valved peelable introducer. The port lumen will not fit through the introducer during the insertion procedure.
***FDA Determined* Cause [2]**	*Unknown/Undetermined by firm*
Action	Medcomp mailed a Customer Notification letter dated February 23, 2017, to all affected customers to inform them of the issue. Customers were asked to examine their inventory and return all unused product. Distributors were also asked to locate the end user/facility of where the affected product was sold and communicate the recall to them. Customers were instructed to contact their customer service representative for a Returned Goods Authorization (RGA) number if necessary at 215-256-4201. Customers were also instructed to complete and return page 2 of the letter by fax to 215-256-9191. For questions regarding *this recall call 215-256-4201*.
Quantity in Commerce	71 units
Distribution	Worldwide Distribution to PR and Panama
Total Product Life Cycle	TPLC Device Report[27]