FDA U.S. FOOD & DRUG ADMINISTRATION

Class 2 Device Recall 6hole Pubic Symphysis plate

See Related Information[22]

Date Initiated by Firm	January 19, 2017
Create Date	February 14, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1199-2017
Recall Event ID	76332[23]
510(K)Number	K122538[24]
Product Classification	Plate, fixation, bone[25] - **Product Code** HRS[26]
Product	6-hole Pubic Symphysis plate (PN 70-0451). The pelvic bone plates for the pelvic ring are a series of plates with varying lengths that function as internal fixation devices for fractures, fusions and osteotomies of the pelvic ring. The plates are strategically pre-contoured where beneficial to the application, and they are secured to the bone with 3.5mm non-locking screws. The Acumed pelvic ring plate is the Pubic Symphysis Plate. The Acumed Pelvic Plating System is intended for use by surgeons with orthopedic training and knowledge of the indications and techniques required for fixation. The device is to be implanted by the surgeon in a sterile operating room setting.
Code Information	Lot number: 383813
Recalling Firm/ Manufacturer	Acumed LLC 5885 NW Cornelius Pass Rd Hillsboro OR 97124-9432
For Additional Information Contact	Business Services or Agent Inventory 503-627-9957 Ext. 4
Manufacturer Reason for Recall	The 6-hole Pubic Symphysis plate (PN 70-0451) is specified to be made of Commercially Pure Titanium (ASTM F67 - CP Grade 4). However, batch 383813 was manufactured out of Titanium Alloy (Ti-6Al- 4V ELI per ASTM F135 Ti alloy) and was distributed.
FDA Determined Cause [2]	Mixed-up of materials/components
Action	Acumed sent an Urgent Medical Device Recall letter dated January 16, 2007, to all affected customers. The firm sent the Urgent Medical Device Recall Initial Notice, dated 1/16/17, to consignees on January 19, 2017. Consignees were instructed to follow special instructions and send survey to RecallNotification@acumed.net. Domestic customers with questions or need to return products to Acumed, please contact Acumed Agent Inventory via email AgentInventory@acumed.net to obtain a Return Material Authorization (RMA) number or contact your agent directly. International customers with questions or need to return products to Acumed, please contact Acumed Business Service via email at BusinessServices@acumed.net or via phone 877-627-9957, choose Option 4 (US and Canada), or call 001-503-627-9957, choose option 4 (outside of US and Canada) have to obtain a Return Material Authorization (RMA) number.