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## Class 2 Device Recall 6hole Pubic Symphysis plate

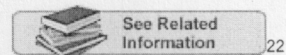


6 510(k) | DeNovo<sup>8</sup> | Registration & | Adverse | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup>  
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 CFR Title 21<sup>16</sup> | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup>

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### Class 2 Device Recall 6hole Pubic Symphysis plate



<b>Date Initiated by Firm</b>	January 19, 2017
<b>Create Date</b>	February 14, 2017
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-1199-2017
<b>Recall Event ID</b>	<u>76332</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K122538</u> <sup>24</sup>
<b>Product Classification</b>	<u>Plate, fixation, bone</u> <sup>25</sup> - <b>Product Code</b> <u>HRS</u> <sup>26</sup>
<b>Product</b>	<p>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.</p> <p>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.</p>
<b>Code Information</b>	Lot number: 383813
<b>Recalling Firm/ Manufacturer</b>	Acumed LLC 5885 NW Cornelius Pass Rd Hillsboro OR 97124-9432
<b>For Additional Information Contact</b>	Business Services or Agent Inventory 503-627-9957 Ext. 4
<b>Manufacturer Reason for Recall</b>	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.
<b>FDA Determined Cause<sup>2</sup></b>	Mixed-up of materials/components
<b>Action</b>	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.