<table>
<thead>
<tr>
<th><strong>Date Posted</strong></th>
<th>July 17, 2014</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recall Status</strong></td>
<td>Open</td>
</tr>
<tr>
<td><strong>Recall Number</strong></td>
<td>Z-2076-2014</td>
</tr>
<tr>
<td><strong>Recall Event ID</strong></td>
<td>6861522</td>
</tr>
<tr>
<td><strong>Premarket Notification 510(K) Number</strong></td>
<td>K13376523</td>
</tr>
<tr>
<td><strong>Product Classification</strong></td>
<td>Cement, Fixation - Product Code JDQ</td>
</tr>
<tr>
<td><strong>Product</strong></td>
<td>Tritium Sternal Plate System, Screw, 0.27mm X 12mm, 12 Pack, Sterile. The Pioneer Surgical Cable Plate System is used in the stabilization and fixation of fractures of the anterior chest wall including Sternal fixation following sternotomy and Sternal reconstructive surgical procedures. The screws are packaged as a 12 pack using a double tray packaging configuration.</td>
</tr>
<tr>
<td><strong>Code Information</strong></td>
<td>Model: 60-27-12-S12 UDI Number: 00849498061463 LOT: 160852 Expiration:12/23/2018</td>
</tr>
<tr>
<td><strong>Recalling Firm/Manufacturer</strong></td>
<td>PIONEER SURGICAL TECHNOLOGY, INC. 375 River Park Cir Marquette, Michigan 49855-1781</td>
</tr>
<tr>
<td><strong>For Additional Information Contact</strong></td>
<td>Dan Nelson 906-226-4812</td>
</tr>
<tr>
<td><strong>Manufacturer Reason for Recall</strong></td>
<td>Lack of Sterility Assurance</td>
</tr>
<tr>
<td><strong>FDA Determined Cause</strong></td>
<td>TRAINING: Employee Error</td>
</tr>
<tr>
<td><strong>Action</strong></td>
<td>On 6/11/14 and 6/12/14 the firm contacted their two consignees and surgeon via phone and explained that the product did not go through the sterilization process. The returns authorization number and shipping labels were discussed for the unused unit. On 6/17/14 and 6/23/14 an URGENT: MEDICAL DEVICE VOLUNTARY RECALL NOTIFICATION was sent to the customers as well as the one surgeon. The latter explained the sterility concerns and that the products were not being recalled. Contact Dan Nelson, Manager of Quality, at 906-226-4466 if you have any questions or concerns.</td>
</tr>
<tr>
<td><strong>Quantity in Commerce</strong></td>
<td>5</td>
</tr>
<tr>
<td><strong>Distribution</strong></td>
<td>US Nationwide Distribution in the states of TX and FL</td>
</tr>
<tr>
<td><strong>Total Product Life Cycle</strong></td>
<td>TPLC Device Report</td>
</tr>
</tbody>
</table>

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
3 510(K) Database: 510(K)s with Product Code = JDQ and Original Applicant = PIONEER SURGICAL TECHNOLOGY, INC.