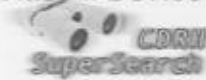


FDA Home<sup>3</sup> Medical Devices<sup>4</sup> Databases<sup>5</sup>

## Class 2 Device Recall Activa PC

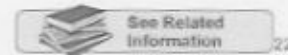


510(k)<sup>6</sup> | DeNovo<sup>7</sup> | Registration & Listing<sup>8</sup> | Adverse Events<sup>9</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | Classification<sup>13</sup> | Standards<sup>14</sup>  
 CFR Title | Radiation-Emitting | X-Ray | Medsun | CLIA<sup>19</sup> | TPLC<sup>20</sup> | Inspections<sup>21</sup>  
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### Class 2 Recall Activa PC



<b>Date Posted</b>	August 18, 2014
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-2259-2014
<b>Recall Event ID</b>	<u>68935</u> <sup>23</sup>
<b>Product</b>	Medtronic, Activa PC, Model 37601, Method of Sterilization: Ethylene Oxide, Single Use Only, Rx Only. The Activa® PC neurostimulator is a dual-channel device capable of delivering bilateral stimulation. Activa PC contains a non-rechargeable battery and microelectronic circuitry to deliver a controlled electrical pulse to precisely targeted areas of the brain. The device is typically implanted subcutaneously near the clavicle, connected to an extension and leads, which are implanted in the brain.
<b>Code Information</b>	Serial numbers: NKM724776H, NKM724782H, NKM724785H, NKM724790H, NKM724802H, NKM724843H.
<b>Recalling Firm/ Manufacturer</b>	Medtronic Neuromodulation 7000 Central Ave Ne Minneapolis, Minnesota 55432-3568
<b>For Additional Information Contact</b>	Medtronic Representative 800-633-8766
<b>Manufacturer Reason for Recall</b>	Medtronic is recalling six Activa PC (model 37601) Implantable Neurostimulators due to the potential for a damaged electrical component during manufacturing.
<b>Action</b>	The firm, Medtronic, notified their Consignees on 07/14/2014 via telephone of the recall. Medtronic representative used telephone script to convey the information. The script was directed to Risk Management or Inventory Management. The caller was to inform consignees of the problem and product being recalled. Advised consignees to quarantine the product and provided the Medtronic Device Removal Reply Form to the consignees via e-mail or Fax. The Reply Form included contact information which was to call 1-800-633-8766 in case they needed to contact a Medtronic representative. The completed form is to be faxed back to 1-800-897-3899 or e-mail a PDF to neuro.quality@medtronic.com. If you have any questions, call 763-526-1294.
<b>Quantity in Commerce</b>	6
<b>Distribution</b>	Distributed in the states of: MA, NC, OH, and TX.

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>24</sup>](#)

#### Links on this page:

1. <http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdomain>
2. <http://www.addthis.com/bookmark.php>
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4. <http://www.fda.gov/MedicalDevices/default.htm>