



[FDA Home](#)<sup>3</sup> [Medical Devices](#)<sup>4</sup> [Databases](#)<sup>5</sup>

**Class 2 Device Recall LifeVest Wearable Defibrillator**

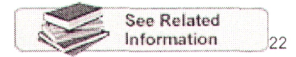


[510\(k\)](#)<sup>6</sup> | [DeNovo](#)<sup>8</sup> | [Registration & Listing](#)<sup>9</sup> | [Adverse Events](#)<sup>10</sup> | [Recalls](#)<sup>11</sup> | [PMA](#)<sup>12</sup> | [HDE](#)<sup>13</sup> | [Classification](#)<sup>14</sup> | [Standards](#)<sup>15</sup> | [CFR Title](#)<sup>21</sup> | [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>

[New Search](#)

[Back to Search Results](#)

**Class 2 Device Recall LifeVest Wearable Defibrillator**



<b>Date Initiated by Firm</b>	September 12, 2017
<b>Create Date</b>	January 14, 2018
<b>Recall Status<sup>1</sup></b>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0353-2018
<b>Recall Event ID</b>	<a href="#">78926</a> <sup>23</sup>
<b>PMA Number</b>	<a href="#">P010030</a> <sup>24</sup>
<b>Product Classification</b>	<a href="#">Wearable automated external defibrillator</a> <sup>25</sup> - <b>Product Code</b> <a href="#">MVK</a> <sup>26</sup>
<b>Product</b>	LifeVest Wearable Defibrillator Model 4000, Product Number 10A0988-A01.  The LifeVest system is indicated for patients 18 years of age and older who are at risk for sudden cardiac arrest and are not candidates for or refuse an implantable defibrillator.
<b>Code Information</b>	All Serial Numbers
<b>Recalling Firm/ Manufacturer</b>	Zoll Manufacturing Corp. 121 Gamma Dr Pittsburgh PA 15238-2919
<b>For Additional Information Contact</b>	Zoll Technical Support 800-543-3267
<b>Manufacturer Reason for Recall</b>	Incorrect service code for properly catching critical defects during self-check. Potential for defibrillation shock failure
<b>FDA Determined Cause<sup>2</sup></b>	Other
<b>Action</b>	On September 14, 2017, ZOLL Manufacturing Corporation issued a patient safety alert notice dated September 12, 2017 to all active patients via courier service. As of November 2, 2017, a copy of this same patient Safety Alert notice is included with all current device shipments. The purpose of the communication is to revise the training patients received about the "Call for service" message. In certain cases, a "Call for service - Message Code 102" could mean that your LifeVest may not be able to deliver therapy if you need it. Users should call ZOLL immediately for a replacement LifeVest if a "Call for service - Message Code 102" appears on the screen. A replacement will be provided within 24 hours. Patients are instructed to continue using the LifeVest as prescribed by their physician.
<b>Quantity in Commerce</b>	33,670 units
<b>Distribution</b>	US Nationwide
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.