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**Class 2 Device Recall Ally Uterine Positioning System (Ally UPS)**

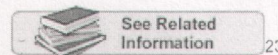


6 510(K) | DeNovo<sup>8</sup> | Registration & Listing<sup>9</sup> | Adverse Events<sup>10</sup> | Recalls<sup>11</sup> | PMA<sup>12</sup> | HDE<sup>13</sup> | Classification<sup>14</sup> | Standards<sup>15</sup>  
 CFR Title | Radiation-Emitting Products<sup>17</sup> | X-Ray Assembler<sup>18</sup> | Medsun Reports<sup>19</sup> | CLIA<sup>20</sup> | TPLC<sup>21</sup> | Inspections<sup>22</sup>  
 21<sup>16</sup>

[New Search](#)

[Back to Search Results](#)

**Class 2 Recall  
 Ally Uterine Positioning System  
 (Ally UPS)**



<b>Date Posted</b>	June 08, 2015
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-1727-2015
<b>Recall Event ID</b>	<a href="#">71308<sup>24</sup></a>
<b>Premarket Notification 510(K) Number</b>	<a href="#">K141523<sup>25</sup></a>
<b>Product Classification</b>	<a href="#">Cannula, Manipulator/Injector, Uterine<sup>26</sup> - Product Code LKF<sup>27</sup></a>
<b>Product</b>	Ally Uterine Positioning System (Ally UPS) used in the mounting and positioning and holding of uterine manipulators during gynecological laproscopic procedures Model: Ally UPS
<b>Code Information</b>	Serial Numbers: 020015;020021;020023; 020043;020051
<b>Recalling Firm/Manufacturer</b>	<a href="#">CooperSurgical, Inc.</a> 75 Corporate Dr Trumbull, Connecticut 06611-1350
<b>For Additional Information Contact</b>	Nana Banafo 203-601-5200 Ext. 3350
<b>Manufacturer Reason for Recall</b>	Design of device may expose user to injury to fingers or body parts
<b>FDA Determined Cause<sup>2</sup></b>	DESIGN: Device Design
<b>Action</b>	CooperSurgical initiated the recall on May 18, 2015 via Fedex with confirmed delivery receipt. The letter identified the affected product and asked users to discontinue use and complete the Acknowledgement and Receipt Form to schedule a replacement. Questions contact 203.601.5200.
<b>Quantity in Commerce</b>	5 units
<b>Distribution</b>	Distributed in the states of CA, IL, NC, and NY.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report<sup>28</sup></a>

<sup>1</sup> For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55<sup>29</sup>](#)

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

**510(K) Database**      [510\(K\)s with Product Code = LKF and Original Applicant = COOPER SURGICAL, INC.<sup>30</sup>](#)

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