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**Class 1 Device Recall Roadrunner Uniglide Hydrophilic Wire Guide**

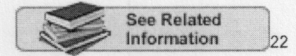


<sup>6</sup> 510(K)|<sup>8</sup> DeNovo<sup>7</sup> | <sup>9</sup> Registration & Listing | <sup>10</sup> Adverse Events | <sup>11</sup> Recalls | <sup>12</sup> PMA | <sup>13</sup> HDE | <sup>14</sup> Classification | <sup>15</sup> Standards | <sup>16</sup> CFR Title 21 | <sup>17</sup> Radiation-Emitting Products | <sup>18</sup> X-Ray Assembler | <sup>19</sup> Medsun Reports | <sup>20</sup> CLIA | <sup>21</sup> TPLC

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**Class 1 Device Recall Roadrunner Uniglide Hydrophilic Wire Guide**



<b>Recall Date</b>	August 25, 2016
<b>Recall Status<sup>1</sup></b>	Open
<b>Recall Number</b>	Z-2537-2016
<b>Recall Event ID</b>	<u>74561</u> <sup>23</sup>
<b>510(K)Number</b>	<u>K110009</u> <sup>24</sup> <u>K130766</u> <sup>25</sup>
<b>Product Classification</b>	<u>Wire, guide, catheter</u> <sup>26</sup> - <b>Product Code</b> <u>DQX</u> <sup>27</sup>
<b>Product</b>	Roadrunner Uniglide Hydrophilic Wire Guide, Catalog Numbers and GPN: HPWA-18-260, G30489; HPWA-18-320, G30490; HPWA-25-260, G30491; HPWA-35-260, G30492; HPWAS-35-260, G30506; HPW-35-150, G56149; HPW-35-180, G56150; HPWS-35-150, G56152; HPWS-35-180, G56153; HPWA-35-80, G56172; HPWA-35-150, G56173; HPWA-35-180, G56174; HPWA-18-180, G56160; HPWAS-35-150, G56176; HPWAS-35-180, G56177. Used with vascular catheter. Roadrunner UniGlide Hydrophilic Wire Guide is constructed from a steerable, metallic core with a polymer coating. A hydrophilic coating is applied over the radiopaque polymer jacket. Sterile- Individual product is packaged in a Tyvek-film sterilizable outer pouch and boxed in a quantity of five.
<b>Code Information</b>	Roadrunner Uniglide Hydrophilic Wire Guide, Catalog Numbers and GPN: HPWA-18-260, G30489; HPWA-18-320, G30490; HPWA-25-260, G30491; HPWA-35-260, G30492; HPWAS-35-260, G30506; HPW-35-150, G56149; HPW-35-180, G56150; HPWS-35-150, G56152; HPWS-35-180, G56153; HPWA-35-80, G56172; HPWA-35-150, G56173; HPWA-35-180, G56174; HPWA-18-180, G56160; HPWAS-35-150, G56176; HPWAS-35-180, G56177.  Lot numbers 6911522, 6911523, 6911524, 6911526, 6911527, 6911528, 6911529, 6911530, 6911533, 6911535, 6911545, 6911549, 6911551, 6911552, 6919676, 6919678, 6919680, 6935843, 6935844, 6935846, 6935848, 6935849, 6935850, 6935851, 6935852, 6935853, 6935855, 6948854, 6948855, 6948856, 6948857, 6948858, 6948860, 6948861, 6948862, 6955228, 6955229, 6955230, 6955231, 6955232, 6955233, 6955234, 6955235, 6955236, 6955237, 6961752, 6961753, 6961754, 6961755, 6961756, 6961757, 6961758, 6961759, 6961760, 6961761, 6965235, 6965236, 6965237, 6965238, 6965240, 6965469, 6965625, 6965626, 6968777, 6968779, 6975365, 6975367, 6975368, 6981022, 6981026, 6981346, 6981347, 6981349, 6981351, 6986896, 6986897, 6986898, 6988487, 6988488, 6992197, 6992198, 6995077, 6995078, 6995080, 6995082, 6995083, 6997860, 6999759, 6999760, 7000724, 7000725, 7000726, 7000727, 7000730, 7000732, 7000733, 7000735, 7012526, 7012527, 7012528, 7012529, 7012530, 7012840, 7015854, 7015855, 7015856, 7015857, 7015897, 7015898, 7015899, 7016252, 7016253, 7019017, 7019018, 7019019, 7019020, 7019022, 7019025, 7019027, 7019491, 7019492, 7019493, 7019494, 7021222, 7021223, 7021224, 7021225, 7021226, 7021227, 7022591, 6948855X, 6955234X, NS6911520, NS6935845, NS6935847, NS6935854, NS6948859, NS6965239, NS6968778, NS6975369, NS6981025, NS6995079, NS6999757, NS6999758, NS6999761, NS7000728, NS7012841, NS7019023, NS7019024, and NS7019495.
<b>Recalling Firm/Manufacturer</b>	Cook Inc. 750 N Daniels Way Bloomington IN 47404-9120
<b>For Additional Information Contact</b>	Stericycle Expert Solutions 866-912-9552

<b>Manufacturer Reason for Recall</b>	Potential coating contamination with glass particles.
<b>FDA Determined Cause <sup>2</sup></b>	Material/Component Contamination
<b>Action</b>	Cook Inc. initiated a voluntary recall of the Roadrunner UniGlide Hydrophilic Wire Guides on June 24, 2016 via courier due to the potential for the device to be contaminated with glass particles. The firm issued a press release dated August 12, 2016. Customers were asked to take the following actions: 1. Examine inventory immediately to determine if you have affected products and quarantine affected products. 2. Return affected products to Stericycle Expert Solutions (a third-party recall administration service provider). Use the enclosed label and a copy of the Acknowledgement and Receipt Form to receive a product credit. 3. Even if you do not have affected products on hand, you must still complete the Acknowledgement and Receipt Form and fax it to 866.796.4780 or email it to cookmedical4502@stericycle.com. 4. Report adverse events to Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. Monday through Friday between 7:30 a.m. and 5:00 p.m. (Eastern Time). Or by email at CustomerRelationsNA@cookmedical.com. Should you have any medical questions or concerns, please contact Cook Medical Customer Relations at 800.457.4500 or 812.339.2235. For information regarding the recall, please contact Stericycle Expert Solutions at 866.912.9552. Cook is providing notification to distributors and informing them that this notice must be shared with appropriate personnel, including down to the user level, within your organization or to any organization where the potentially affected devices have been transferred.
<b>Quantity in Commerce</b>	8,750 devices were distributed in commerce
<b>Distribution</b>	Worldwide distribution. US (nationwide), Australia, Austria, Belgium, Canada, China, Czech Republic, France, Germany, Hong Kong, Hungary, Italy, Jordan, Korea, Spain, South Africa, Taiwan, Turkey, and United Kingdom
<b>Total Product Life Cycle</b>	<u>TPLC Device Report</u> <sup>28</sup>

<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 = DQX and Original Applicant = COOK, INC.<sup>30</sup>

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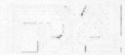
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