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### Class 2 Device Recall staple, implantable

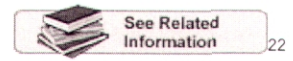


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### Class 2 Device Recall staple, implantable



|   |   |
|---|---|
| <b>Date Initiated by Firm</b>             | September 15, 2017  |
| <b>Create Date</b>                        | March 06, 2018  |
| <b>Recall Status</b> <sup>1</sup>         | Open <sup>3</sup> , Classified  |
| <b>Recall Number</b>                      | Z-0908-2018   |
| <b>Recall Event ID</b>                    | <a href="#">79166</a> <sup>23</sup>   |
| <b>510(K)Number</b>                       | <a href="#">K132493</a> <sup>24</sup>   |
| <b>Product Classification</b>             | <a href="#">Staple, implantable</a> <sup>25</sup> - <a href="#">Product Code GDW</a> <sup>26</sup>  |
| <b>Product</b>                            | <p>Endo GIA" Radial Reload with Tri-Staple" Technology</p> <p>The Endo GIA radial reloads with Tri-Staple Technology have application in open or minimally invasive general abdominal, gynecologic and thoracic surgery for resection and transection of tissue and creation of anastomosis, as well as application deep in the pelvis, e.g. low anterior resection. They may be used for transection and resection of liver substance, hepatic vasculature and biliary structures and for transection and resection of pancreas.</p> |
| <b>Code Information</b>                   | Product number: EGIARADXT, Lot code: N6L0351X   |
| <b>Recalling Firm/Manufacturer</b>        | Covidien LLC<br>60 Middletown Ave<br>North Haven CT 06473-3908  |
| <b>For Additional Information Contact</b> | Catherine T. Wrenn<br>203-492-5000  |
| <b>Manufacturer Reason for Recall</b>     | The device cartridge disengaged during use due to manufacturing error.  |
| <b>FDA Determined Cause</b> <sup>2</sup>  | Process control   |
| <b>Action</b>                             | Medtronic sent an "URGENT MEDICAL RECALL LETTER" dated September 13, 2017, was issued to customers titled "Covidien Endo GIA Black Radial Reload with Tri-Staple Technology" urging customers to quarantine and return unused product to recalling firm. Questions or concerns can be directed to: <a href="mailto:feedback.customerservice@Covidien.com">feedback.customerservice@Covidien.com</a> . For further questions, please call (203) 492-5000.  |
| <b>Quantity in Commerce</b>               | 163   |
| <b>Distribution</b>                       | Internationally, including Japan. No USA Customers  |
| <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. Learn more about [medical device recalls](#)<sup>28</sup>.