FDA

Class 2 Device Recall staple, implantable

See Related Information[22]

Date Initiated by Firm	September 15, 2017
Create Date	*March 06, 2018*
Recall Status[1]	Open[3], Classified
Recall Number	Z-0908-2018
Recall Event ID	79166[23]
510(K)Number	K132493[24]
Product Classification	Staple, implantable[25] - **Product Code** GDW[26]
Product	Endo GIA" Radial Reload with Tri-Staple" Technology 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.
Code Information	Product number: EGIARADXT, Lot code: N6L0351X
Recalling Firm/ Manufacturer	Covidien LLC 60 Middletown Ave North Haven CT 06473-3908
For Additional *Information Contact*	Catherine T. Wrenn *203-492-5000*
Manufacturer Reason for Recall	The device cartridge disengaged during use due to manufacturing error.
FDA Determined Cause [2]	*Process control*
Action	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: feedback.customerservice@Covidien.com. For further questions, please call (203) 492-5000.
Quantity in Commerce	*163*
Distribution	Internationally, including Japan. No USA Customers
Total Product Life Cycle	TPLC Device Report[27]

[1] 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[28].