Class 2 Device Recall staple, implantable

Date Initiated by Firm
September 15, 2017

Create Date
March 06, 2018

Recall Status
Open, Classified

Recall Number
Z-0906-2018

Recall Event ID
791663

510(k)Number
K13249324

Product Classification
Staple, implantable - Product Code GDW60

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: NBL0351X

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
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.custsupport@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

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 is updated for a final time when the recall is terminated.

Learn more about medical device recalls.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=161502

3/12/2018