Class 2 Device Recall Medtronic

See Related Information [22]

Recall Date	August 15, 2016
Recall Status[1]	Open
Recall Number	Z-2541-2016
Recall Event ID	74672[23]
510(K)Number	K063091[24]
Product Classification	Mesh, surgical, polymeric[25] - **Product Code** FTL[26]
Product	TRYX Neuro Absorbable Antibacterial Envelope Product Usage: Indicated for stabilization of implanted pacemakers (IPG) and/or implantable cardioverter defibrillators (ICD)
Code Information	model number NMRM6122 lot number 16E03727 16E05728 model number NMRM6133 lot number 16E02726 16E09730
Recalling Firm/ Manufacturer	TYRX Inc. 1 Deerpark Dr Ste G Monmouth Junction NJ 08852-1920
For Additional Information Contact	Mr. Carlos Alfonzo 732-246-8676
Manufacturer Reason for Recall	TRYX products are being recalled since the processes of spaying, welding, drying oven and polymer were not adequately validated.
FDA Determined Cause [2]	Process control
Action	Medtronic sent an Urgent Medical Device Recall letter dated June 2016 to affected customers. The letter identified the affected product problem and actions to be taken. Customers are asked to immediately remove and quarantine all unused product that remains in inventory, return unused product to Medtronic and contacted the local Medtronic representative or Customer Service at 800-848-9300 to assist with the return and credit of unused product. Medtronic will provide credit for all non-expired, unused product. The