Class 2 Device Recall Axium Bare Detachable Coil System

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Date Initiated by Firm	April 27, 2022
Create Date	June 13, 2022
Recall Status[1]	Open[3], Classified
Recall Number	Z-1261-2022
Recall Event ID	90178[23]
510(K)Number	K203432[24]
Product Classification	Device, neurovascular embolization[25] - **Product Code** HCG[26]
Product	AXIUM DETACHABLE COIL SYSTEM REF QC-4-12-HELIX; Axium Detachable Coil System REF QC-10-30-3D;
Code Information	Product Number: QC-4-12-HELIX UDI-DI (GTIN) Code: 00847536029590 Lot Number: B240079 Product Number: QC-10-30-3D UDI-DI (GTIN) Code: 00847536030138 Lot Number: B240084
Recalling Firm/ Manufacturer	Micro Therapeutics, Inc. 9775 Toledo Way Irvine CA 92618-1811
Manufacturer Reason for Recall	Due to incorrect size and configuration labeling of the detachable coil system.
FDA Determined Cause [2]	Labeling Change Control
Action	On 04/27/2022, Medtronic initiated distribution of a retrieval notice via mail courier service to impacted OUS Consignees (hospital accounts) informing them that Medtronic has received reports that the incorrect size of Axium Detachable Coil System were found in device packages and has identified that two (2) production lots have been incorrectly labelled. Customers are asked to immediately take the following actions: 1. Do NOT use any impacted product. Remove and quarantine all unused impacted products in your inventory. 2. Return the impacted products to Medtronic. Your Medtronic representative may assist in facilitating the return of product as necessary. If alternative product is needed, your Medtronic representative can assist you with identifying suitable replacement product. 3. Complete and return the Customer Confirmation Form enclosed in this letter

	acknowledging that you have received this information. Questions should be addressed to Medtronic representatives or email the Office of Medical Affairs at rs.nvoma@medtronic.com.
Quantity in Commerce	96 systems
Distribution	International distribution in the countries of China and Republic of Korea.
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].

[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

510(K) Database	510(K)s with Product Code = HCG and Original Applicant = Micro Therapeutics, Inc. d/b/a ev3 Neurovascular[29]

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28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=HCG&knumber=&applicant=Micro%20Therapeutics%2C%20Inc%2E%20d%2Fb%2Fa%20ev3%20Neurovascular

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