Class 2 Device Recall Medtronic, Lead Kit for DBS Stimulation

See Related Information[22]

Recall Date	August 19, 2016
Recall Status[1]	Open
Recall Number	Z-2602-2016
Recall Event ID	74545[23]
PMA Number	P960009[24]
Product Classification	Stimulator, electrical, implanted, for parkinsonian tremor[25] - **Product Code** MHY[26]
Product	Medtronic, Lead Kit for DBS Stimulation. Model Numbers 3387S-40 (p/n 3387S0007V) & 3389S-40 (p/n 3389S0008V).
Code Information	lots: VA15GPJ, VA15K3N, VA15K7K
Recalling Firm/ Manufacturer	Medtronic Neuromodulation 7000 Central Ave Minneapolis MN 55421-1241
For Additional Information Contact	Medtronic Technical Services 800-707-0933
Manufacturer Reason for Recall	Medtronic has voluntarily decided to retrieve unused Model 3387S-40 and 3389S-40 DBS leads from three manufacturing lot numbers. During the manufacturing process of a DBS lead component, Medtronic identified the potential for lead insulation damage.
FDA Determined Cause [2]	Process design
Action	Consignees were delivered in person by Medtronic Field Representatives a "Medical Device Removal" letter dated June 2016. The letter described the problem and the product involved in the recall. Advised consignees to return the unused product and to complete the Customer Confirmation Form. For questions contact Medtronic Technical Services at 800-707-09033 weekdays 7 am - 6 pm, or contact your Medtronic representative.
Quantity in Commerce	70
Distribution	US: AR, CA, FL, IL MD, MO, NE, NY, OH, TN WI.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

PMA Database PMAs with Product Code = MHY and Original Applicant = MEDTRONIC Inc.[29]

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