Class 2 Device Recall Medtronic, Lead Kit for DBS Stimulation

Recall Date: August 19, 2016
Recall Status: Open
Recall Number: Z-2602-2016
Recall Event ID: 7454523
PMA Number: P96000924

Product Classification: Stimulator, electrical, implanted, for parkinsonian tremor - Product Code MHV26


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: 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

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1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.52.
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.

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