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Enforcement Report - Week of April 17, 2013

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Product Detail

Product Description	Medtronic MiniMed Paradigm Insulin Infusion Pumps Model Numbers: MMT-511, MMT-512, MMT-712, MMT-712E, MMT-515, MMT-715, MMT-522, MMT-522K, MMT-722, MMT-722K, MMT-523, MMT-523K, MMT-723, MMT-723K, MMT-554, and MMT-754. Product Usage: Paradigm insulin infusion pumps are intended for use to deliver basal and bolus insulin to persons with diabetes.
Recall Number	Z-1085-2013
Classification	Class II
Code Info	Not available
Product Distributed Qty	428,000 units
Reason For Recall	Medtronic is recalling the Medtronic Paradigm Insulin Pump because the pump's drive support cap may become detached from the pump case and protrude from the lower right side of the pump. When the pump is expose to water it may result in damage to the pump's internal electronics. This moisture damage can prevent the pump's buttons from working properly or can cause the pump to alarm.

Event Detail

Event Id	64754
Product Type	Devices
Status	Ongoing
Recalling Firm	Medtronic MiniMed
City	Northridge
State	CA
Country	US
Voluntary / Mandated	Voluntary: Firm Initiated
Recall Initiation Date	2013-03-22
Initial Firm Notification of Consignee or Public	Letter
Distribution Pattern	Worldwide Distribution - USA (nationwide) the countries of: AE, AR, AT, AU, BA, BH, BM, BR, BS, CA, CH, CL, CN, CO, CR, CY, CZ, DE, DK, DO, DZ, EC, EE, EG, ES, FI, FR, GB, GR, GT, HK, HR, HU, IE, IL, IN, IQ, IT, JO, JP, KR, KW, LB, LC, LV, MK, MX, MY, NL, NO, NZ, OM, PA, PE, PL, PR, PY, QA, RO, SA, SE, SG, SI, SK, SV, SY, TF, TH, TR, TT, TW, UA, UY, VE, ZA.

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U.S. Food and Drug Administration
 10903 New Hampshire Avenue
 Silver Spring, MD 20993
 Ph. 1-888-INFO-FDA (1-888-463-6332)

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