FDA

Class 2 Device Recall Zenex

See Related Information[22]

Date Initiated by Firm	August 28, 2017
Create Date	November 19, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0036-2018
Recall Event ID	78093[23]
Product Classification	implantable pacemaker Pulse-generator[24] - **Product Code** DXY[25]
Product	PM 1250 and PM 2250 ZENEX; PM1282 and PM2282 ZENEX MRI These low voltage (LV) devices are implantable pacemaker pulse generators, intended to be permanently implanted in the body, that have a power supply and electronic circuits that produce a periodic electrical pulse to stimulate the heart. These devices are used as a substitute for the heart's intrinsic pacing system to correct both intermittent and continuous cardiac rhythm disorders.
Code Information	4875733, 4875547, 4875731, 4875734, 4875544, 4727698, 4767620, 4796861, 4736677, 4727718, 4727695, 4727691, 4727709, 4727693, 4727694, 4727692, 4727665, 4727720, 4783266, 4796865, 4875549, 4796863, 4796864, 4767614, 4767602, 4767618, 4767603, 4767610, 4736662, 4736687, 4736637, 4727697, 4783271, 4885023, 4875726, 4875546, 4784007, 4783258, 4875550, 4875720, 4784005, 4885066, 4885039, 4885068, 4783268, 4875551, 4781138, 4784000, 4784003, 4885069, 4885070, 4885009, 4885002, 4885015, 4885013, 4885027, 4784004, 4885024, 4748635, 4748609, 4748612, 4796551, 4748617, 4748606, 4748601, 4748616, 4748613, 4780600, 4875543, 4885076, 4727719, 4885031, 4885034, 4884998, 4875545, 4875721, 4884996, 4885077, 4884983, 4885065, 4875540, 4885012, 4781151, 4874050, 4875722, 4875728, 4736664, 4736651, 4781139, 4736650, 4736678, 4736668, 4736653, 4736656, 4780595, 4736647, 4781114, 4783280, 4873505, 4874054, 4874048, 4874061, 4874047, 4874051, 4874052, 4727710, 4736646, 4736670, 4885075, 4736671, 4781136, 4736657, 4736659, 4781146, 4781110, 4736665, 4736655, 4736682, 4736683, 4736679, 4874055, 4736648, 4736649, 4780602, 4781117, 4736660, 4781111, 4781199, 4736652, 4736674, 4736672, 4736689, 4727722, 4874058, 4783263, 4736680, 4736676, 4783281, 4783289, 4767595, 4727676, 4727699, 4727679, 4873508, 4727670, 4873504, 4727667, 4727668, 4727675, 4727666, 4727689, 4727673, 4727583, 4727690, 4727696, 4727678, 4727669, 4873514, 4873509, 4874056, 4874053, 4874057, 4874049, 4873501, 4873513, 4874059, 4873511, 4873506, 4783282, 4873512, 4780644, 4783265, 4783274, 4783287, 4781192, 4783278, 4736658, 4783272, 4783288, 4873510, 4874060, 4873507, 4908385, 4908360, 4908390, 4908389, 4913428, 4908388, 4908363, 4908376, 4908383, 4908381, 4908374, 4908371, 4908369, 4908379, 4908366, 4908355, 4908364, 4908358, 4908357, 4908380, 4908392, 4908386, 4908377, 4908384, 4908370, 4908368, 4908359, 4908367, 4913424, 4908382, 4908378, 4908361, 4908362, 4908365, 4908375, 4908372, 4908373, 4908354, 4908391, 4913412, 4913421, 4913426, 4913416, 4908356, 4913423, 4913422, 4913427, 4908387, 4913414, 4913415, 4913418, 4913417, 4913419, 4913413, 4913425, 4913429, 4913420, 4915147, 4915145, 4915144, 4915143, 4800743, 4915148, 4903901, 4904137, 4915149, 4904145, 4904138, 4904130, 4903905, 4903909, 4904139, 4904143, 4903885, 4904141, 4903904, 4903878, 4903884, 4903898, 4904134, 4767037, 4749239, 4748581, 4780150, 4780585, 4749248, 4780148, 4767036, 4749249, 4767035, 4728078, 4728066, 4728081, 4728077, 4728071, 4728072, 4728073, 4749246, 4728076, 4728080, 4728074, 4767034, 4780581, 4728068, 4749245, 4749241, 4749235, 4748576, 4749236, 4749240, 4728079, 4767038, 4749243, 4767040, 4749242, 4749238, 4728070, 4728067, 4728069, 4728075, 4749244, 4749247, 4748580, 4748583,

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Recalling Firm/ Manufacturer	St Jude Medical Inc. 15900 Valley View Ct Sylmar CA 91342-3577
For Additional Information Contact	Candace Steele Flippin 651-756-6293
Manufacturer Reason for Recall	New pacemaker firmware was developed to further mitigate the risk of unauthorized access to our pacemakers that utilize radio frequency (RF) communications.
FDA Determined Cause [2]	Unknown/Undetermined by firm
Action	Abbott sent an Important Cybersecurity Advisory dated August 28, 2017, to all affected customers to notify customers of the availability of the programmer software update and associated pacemaker firmware update. The notification material is in the form of a Physician Letter and Hospital Letter and will be delivered to physicians and hospitals with inventory in the US by overnight service. Customers with questions were instructed to contact their Abbott representative or the customers technical support hotline at 1-800-722-3774.
Quantity in Commerce	4828 units
Distribution	Worldwide Distribution
Total Product Life Cycle	TPLC Device Report[26]

[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[27].
[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.

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