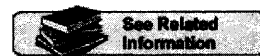


FDA[FDA Home](#)³ [Medical Devices](#)⁴ [Databases](#)⁵**Class 2 Device Recall Accent family of pacemakers**

[510\(k\)](#)⁶ | [DeNovo](#)⁸ | [Registration & Listing](#)⁷ | [Adverse Events](#)¹⁰ | [Recalls](#)¹¹ | [PMA](#)¹² | [HDE](#)¹³ | [Classification](#)¹⁴ | [Standards](#)¹⁵ | [CFR Title 21](#)¹⁶ | [Radiation-Emitting Products](#)¹⁷ | [X-Ray Assembler](#)¹⁸ | [Medsun Reports](#)¹⁹ | [CLIA](#)²⁰ | [TPLC](#)²¹

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Date Initiated by Firm	August 28, 2017
Create Date	October 24, 2017
Recall Status¹	Open ³ , Classified
Recall Number	Z-0035-2018
Recall Event ID	<u>78093</u> ²³
PMA Number	<u>P880086S283</u> ²⁴
Product Classification	<u>Implantable pulse generator, pacemaker (non-CRT)</u> ²⁵ - Product Code <u>LWP</u> ²⁶
Product	PM1226 ACCENT ST MRI SR RF and PM2222 ACCENT ST 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	Serial Numbers: 2736872, 2736871, 2736870, 2736874, 2736873, 2538305, 2538304, 2538301, 2538306, 2538307, 2538302, 2512808, 2512812, 2512811, 2384089, 2512807, 2384108, 2384112, 2397881, 2393253, 2393254, 2401631, 2512803, 2401623, 2401617, 2512810, 2384086, 2384126, 2384101, 2384122, 2384121, 2384105, 2384096, 2384098, 2384116, 2384110, 2384111, 2384120, 2384082, 2384085, 2384123, 2384124, 2384107, 2384117, 2384087, 2384097, 2384077, 2393264, 2384115, 2384119, 2384114, 2384104, 2384100, 2384078, 2384092, 2384081, 2384084, 2397878, 2401620, 2384080, 2384079, 2384099, 2401621, 2401624, 2384083, 2512819, 2512818, 2401626, 2401622, 2397879, 2397872, 2393252, 2393259, 2401619, 2401618, 2401629, 2397874, 2397880, 2401628, 2384106, 2393255, 2393256, 2393257, 2512802, 2512805, 2512800, 2512817, 2512801, 2512804, 2512813, 2512814, 2512815, 2512816, 2512806, 2512809, 2384102, 2384095, 2384125, 2384113, 2384103, 2393262.
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 Cause²	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.

Codes for St Jude Medical Inc. recall

1) Zenex: PM 1250 and PM 2250 ZENEX; PM1282 and PM2282 ZENEX MRI

Code Information : 634363, 4634359, 4634346, 4666839, 4636848, 4666240, 4666246, 4583300, 4661228, 4595436, 4641831, 4641828, 4668086, 4558995, 4545150, 4582964, 4666256, 4552832, 4666247, 4656241, 4597320, 4601902, 4668078, 4510018, 4582972, 4559000, 4540193, 4636851, 4634336, 4582961, 4634757, 4638507, 4666833, 4638504, 3120785, 4462723, 3139864, 3146352, 3146613, 3136836, 3105809, 3157035, 4465785, 3154508, 3147616, 3090073, 3130804, 4455679, 3118367, 3090067, 3102333, 4638483, 4465793, 4465872, 3086955, 3086954, 3146617, 3124407, 3146616, 4465783, 3139856, 4456627, 3089900, 4465801, 3131173, 2960116, 4621330, 4656234, 4656215, 4638515, 4668083, 4632936, 2919976, 4634780, 4666249, 4638512, 4632939, 4632929, 4668070, 4641846, 4510858, 4634348, 3104678, 4464607, 3099157, 3101800, 3104688, 3104699, 3120779, 4634753, 3086968, 4666255, 4464360, 4464355, 2956557, 4636849, 4601964, 3120299, 3128369, 3105862, 4465784, 3131159, 3101799, 3131158, 3101804, 3089408, 3116274, 3141709, 3086978, 4464626, 3111178, 3120295, 3096398, 3097824, 3105858, 3116271, 3096411, 3101787, 3139843, 3146351, 4481071, 3102319, 3099856, 3090069, 3116247, 3141730, 3111180, 3141739, 3141694, 3141743, 3118371, 3139857, 3104692, 3116264, 3139836, 3139833, 3125615, 3139872, 3105868, 3131161, 3147600, 4462721, 4462690, 3115077, 4464356, 4464588, 3089402, 3115086, 4634787, 3099156, 3089416, 3126482, 3100090, 3105863, 3102313, 3148271, 3124391, 3115084, 3141736, 3096419, 3086966, 3148280, 3113558, 3125624, 4632940, 4638500, 4638502, 4656240, 4656216, 4656220, 4638496, 4634343, 4582982, 4508005, 4601966, 4634774, 4582969, 4634765, 4659172, 4656238, 4661235, 4552835, 4599668, 4641817, 4641837, 4641820, 4599675, 4666238, 4510880, 4656230, 4641826, 4666832, 4666237, 4621329, 4659164, 4621328, 3141712, 4641843, 4552847, 3118377, 3096800, 3104689, 4634798, 3104700, 4582984, 4634332, 4615392, 4641822, 4604142, 4668065, 4615421, 3089405, 4548061, 4582988, 4638517, 4668068, 4615406, 4666260, 4641835, 4641830, 4638493, 4638495, 4582966, 4510863, 4582978, 4597321, 4634751, 4666245, 4634795, 4638477, 4659163, 4636842, 4615426, 4666837, 4634353, 4666244, 4641823, 4661233, 4634356, 4668079, 4659166, 4582980, 4583314, 4589127, 4668073, 4661227, 4632937, 4597328, 4668066, 4661241, 4661238, 4615434, 4641840, 4632924, 4632932, 4634767, 4615438, 4641833, 4634329, 4634772, 4634335, 4538402, 4656225, 4638480, 4536308, 4545151, 4666248, 4634749, 4634797, 4634347, 4666836, 4641834, 4615419, 4634760, 4638476, 4659162, 4638490, 4666254, 4661236, 4668088, 4583296, 4634341, 4641829, 4641845, 4634345, 4666235, 4634362, 4641836, 4638513, 4545157, 4615402, 4634339, 4656242, 4641849, 3139829, 3126484, 3141735, 3086944, 3120310, 3104693, 3116255, 3139854, 3139838, 3118388, 3118372, 3128452, 3141742, 3141686, 3141731, 3139862, 3116262, 3148287, 3148283, 3089411, 3101790, 3131163, 3128445, 3120306, 3089719, 3097797, 3119353, 3119359, 3096807, 3097828, 3120778, 3097802, 3141687, 3125619, 3124412, 3104686, 3150102, 3143266, 3141688, 3115074, 3102335, 3131165, 3128366, 3089908, 3141733, 4638492, 4656227, 3131178, 3124403, 3148602, 3122112, 3139852, 3115087, 3147609, 3130796,

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2) **Assurity, Assurity: Assurity Model Numbers: PM1240, PM2240; Assurity + Model Number: PM2260; Accent Model Numbers: PM1210, PM2210, PM1222, PM2212; Accent MRI Model Numbers: PM1224, PM2218, PM2224**

Code Information: 3168022, 3168137, 3168131, 3166949, 3169264, 3168170, 3168174, 3168160, 3168152, 3168151, 3168167, 3169262, 3168169, 3168156, 3168136, 3168128, 3168140, 2997899, 2997900, 2997907, 2997898, 2997912, 2997909, 2997911, 2997908, 2996791, 2997910, 2997906, 2997904, 2997905, 2997902, 3061423, 3061408, 2996790, 3004930, 2996788, 2996785, 2996793, 3033816, 3009132, 3007725, 3007721, 3009133, 3007723, 3007722, 3009129, 3009131, 3003098, 3048921, 3025662, 3004935, 3004936, 2996782, 3046111, 2996786, 3003097, 3003096, 3003095, 3061428, 3041550, 2987913, 2996792, 2988949, 2988953, 2988946, 2988948, 2988947, 2988944, 2988950, 3059831, 2988951, 3059833, 2987912, 2987915, 2987920, 2987919, 2987917, 2987916, 2987914, 2987921, 2987918, 2988952, 2991907, 2996787, 2996779, 2996780, 2996783, 3009130, 2996789, 3010136, 2994965, 3041547, 2991905, 2996784, 2991910, 2991903, 2991911, 2990510, 2990504, 2990507, 2990506, 2990503, 2990501, 3043418, 3025661, 3025636, 3010151, 3048902, 3039056, 3056068, 3055750, 3036094, 3036097, 3048947, 3033756, 3043412, 3055700, 3046100, 3014109, 2988945, 3061424, 3025638, 3025679, 3025657, 3010129, 3041555, 3055703, 3039068, 3048939, 3007720, 3039061, 3061413, 3061412, 3055978, 3061426, 3032377, 3048960, 3025653, 3004937, 3004933, 3059827, 3010156, 3061407, 3043408, 3061433, 3033840, 3033764, 3010124, 3010148, 3025645, 3010139, 3010158, 3010150, 3010144, 3010130, 3010128, 3010147, 3010152, 3010133, 3010145, 3010149, 3010137, 3025650, 3010132, 2986787, 3010134, 3010140, 3010161, 3010142, 3010138, 3014123, 3025642, 3025672, 2973982, 3039067, 3025682, 3014121, 3014111, 3014097, 3010162, 3014090, 3010127, 3014114, 3014102, 3014099, 3014095, 3032393, 3010160, 3010141, 3010157, 3010154, 3014107, 3033760, 3039063, 3048936, 3025659, 2941639, 3033758, 3025663, 2973983, 3039057, 3043417, 3025654, 3055674, 3061395, 3033763, 3033759, 3055754, 3033755, 3048909, 3048925, 3048964, 3061384, 3043410, 3025678, 3033773, 3033831, 3033766, 3061414, 3061389, 3032385, 3033814, 3033835, 3032378, 3033819, 3048950, 3039062, 3033765, 3041561, 3033824, 3033767, 3010135, 3033836, 3033752, 3061429, 3041556, 3059832, 3048899, 2941187, 2967585, 3025671, 3025649, 3033837, 3061405, 3010143, 2965666, 3041548, 3025667, 3033776, 3036092,

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3) **Anthem, Allure: Anthem Model Numbers: PM3210, PM3212; Allure/Relieve Model Numbers: PM3222, PM3242, PM3262, PM3542, PM3224, PM3244**

Code Information: 7704300, 3059072, 3054268, 7919992, 7920304, 7817967, 7817955, 3138514, 3138511, 3138526, 3138509, 3138508, 3054263, 7818447, 3054273, 7817983, 3054267, 3054266, 3054265, 3054264, 3054271, 3054270, 3054269, 3054262, 7817951, 7817977, 3123103, 3054272, 7709455, 7701517, 7701661, 7701663, 7701505, 7701512, 7701511, 7701659, 7694197, 7693980, 7694825, 7704282, 7709461, 7704713, 7709452, 7709198, 7704722, 7704786, 7701846, 7704714, 7817993, 7704701, 7704451, 7704449, 7704443, 7709462, 7701531, 7704703, 7704444, 7704303, 7704301, 7701652, 7701525, 7701519, 7701516, 7701936, 7701935, 7701662, 7701507, 7704784, 7709195, 7708977, 7707999, 7707997, 7704787, 7704450, 7704302, 7701527, 7704437, 7704720, 7701924, 7709197, 7666335, 7620796, 7620791, 7620787, 7605801, 7620764, 7620810, 7650930, 7602703, 7620773, 7667329, 7667362, 7667116, 7666329, 7666331, 7638805, 7771255, 7621841, 7602709, 7639600, 7667114, 7600423, 7603336, 7603350, 7603349, 7600997, 7599086, 7622361, 7601702, 7602365, 7667079, 7620770, 7622313, 7620804, 3043349, 7601205, 7920537, 7764011, 7764009, 7764007, 7764016, 7551135, 7549660, 7618230, 7920970, 7764676, 7899203, 7920192, 7899200, 7888712, 7899209, 7898910, 7898790, 7919986, 7764647, 3043395, 7757408, 7757429, 7765061, 7765089, 7764677, 7742680, 7764014, 7764655, 7764662, 7764652, 7764661, 7764694, 7764675, 7764693, 7764653, 7667160, 7764663, 7667765, 3043391, 3043359, 3043346, 3043372, 3046741, 7640649,

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4) **Assurity: PM 1260 ASSURITY +**

Code Information: 45613, 2846353, 2831556, 4457496, 4462698, 4475370, 4457490, 4457515, 4457521, 4452584, 4457523, 2845628, 4464383, 4475399, 2817364, 2831560, 2831564, 2846338, 4456612, 4429258, 4457511, 4457495, 2878511, 2855005, 2855002, 2854974, 2855033, 2878492, 2878503, 2894442, 2880067, 2836154, 2888730, 2893450, 2893429, 2893448, 2831545, 2817703, 2880141, 2846374, 2822832, 2825197, 2827252, 2827254, 2817363, 2831555, 2846364, 2845607, 2846385, 2846386, 2845612, 2846343, 2846340, 2845610, 2845602, 2894443, 2832942, 2915715, 2912143, 2912132, 2915002, 2915030, 2915031, 2915041, 2894440, 2915036, 2912119, 2915717, 4475364, 4456621,

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5) Allure Quadra: PM3544 QUADRA RELIEVE and PM3562 QUADRA ALLURE MP

Code Information: , 4897529, 4897876, 4897589, 4897579, 4800825, 4793664, 4897880, 4897882, 4897527, 4897884, 4897889, 4888034, 4897886, 4880551, 4897514, 4806887, 4799294, 4880283, 4880550, 4880659, 4880661, 4880670, 4880570, 4880280, 4880627, 4836570, 4886070, 4885050, 4885060, 4884434, 4884432, 4884430, 4885057, 4885742, 4885063, 4885061, 4886077, 4888041, 4885761, 4886072, 7841564, 7841543, 7873208, 7896791, 7873206, 7841397, 7896792, 7896807, 7896808, 4880676, 4888029, 7896804, 4788528, 4886062, 4880630, 4887874, 4888068, 4880291, 4881765, 4880588, 4880641, 4880548, 4806885, 4809763, 4885743, 4794364, 4885752, 4886726, 4886744, 4837326, 4885759, 4794376, 4802370, 4831710, 4885046, 4885755, 4886067, 4880623, 4798959, 4885062, 4880261, 4907869, 4880271, 4882448, 4882450, 4887890, 4881759, 4887887, 4884440, 4884429, 4885059, 4885055, 4880289, 4767574, 4881758, 4903863, 4903861, 4904188, 4904185, 4882449, 4882446, 4897522, 7842073, 4880262, 4880609, 4884441, 4887998, 4888023, 4888027, 4888056, 4880290, 4880282, 4880255, 4908025, 4907537, 4897528, 4908031, 4907864, 4880567, 4881771, 4880549, 4880257, 4887888, 4887994, 4897530, 4886073, 4908530, 4907535, 4880263, 4880264, 4880287, 4887987, 4887992, 4881769, 4907536, 4884437, 4908665, 4880652, 4880603, 4880565, 4880258, 4881773, 4880658, 4908527, 4880590, 4903872, 4897526, 4881774, 4880601, 4888069, 4907531, 4903857, 4908523, 4880668, 4908660, 4903858, 4903860, 4903859, 4903874, 4881772, 4881776, 4903868, 4907534, 4897881, 4897875, 4885751, 4887989, 4887894, 4888020, 4888062, 4888030, 4888009, 4897583, 4880297, 4897517, 4897518, 4881763, 4880660, 4881770, 4888026, 4887979, 4886733, 4907533, 4897580, 4881764, 4831701, 4903865, 4870917, 4871254, 4880626, 4870911, 4794366, 4831686, 4796552, 4832735, 4838074, 4795215, 4809734, 4874254, 4838490, 4867289, 7843412, 4795210, 4789592, 4866966, 4806317, 4867305, 4871212, 4809736, 4842213, 4788610, 4794387, 4806307, 4796797, 4841523, 4798061, 4866975, 4796569, 4871220, 7842080, 7840600, 7824427, 7841395, 7824445, 7873581, 7841541, 7825755, 7825768, 4839307, 7840586, 7824453, 7841228, 7841548, 7824444, 7842067, 7824431, 7902608, 7902610, 7896793, 7873583, 7842381, 7896800, 7896799, 7824458, 7841900, 7841304, 7824434, 7873207, 7902612, 7824433, 7824429, 7873210, 4880267, 4880615, 4809759, 4884435, 4880614, 4872137, 4874232, 4881766, 4887872, 4888070, 4887975, 4841529, 4880583, 4880585, 7904604, 4880628, 4841544, 4880293, 4837342, 4887983, 4880600, 4880616, 4883235, 4888032, 4887896, 7904610, 4809757, 4887878, 4801895, 4880645, 4880572, 4883095, 4883104, 4883088, 4882462, 4880607, 4882458, 7902605, 4795652, 4886731, 4767714, 4908525, 4903871, 7841928, 4880672, 4872162, 4909676, 4802377, 4886418, 4886412, 4887985, 4904186, 4904187, 4888001, 4903862, 4886414, 4888060, 4887884, 4788632, 4867302, 4810896, 4842503, 4880260, 4880605, 4874256, 4838386, 4832706, 4841535, 4841541, 4839285, 4866629, 4867046, 4885750, 7904601, 7841314, 4866970, 4866974, 4867148, 4885756, 4885049, 4886750, 4796556, 4831698, 4871265, 4871209, 4881768, 4883105, 4866976, 4874243, 4880663, 4809772, 4883099, 4883236, 4880298, 4867295, 4885748, 4888035, 7904600, 4880667, 4806095, 4883087, 4886061, 4874250, 4888024, 4882455, 4880671, 4880669, 4880569, 4832702, 4887873, 4874227, 4874421, 4874418, 4874234,

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6) MerlinHome: Merlin@Home Software Model EX2000 v8.2.2 for Merlin@Home Transmitter Models EX1150, EX1150W, EX1100, and EX1100W

Code Information: Model EX1100 - GTIN 05414734504782 and Model EX1150 - GTIN 05414734404334

7) Accent family of pacemakers: PM1226 ACCENT ST MRI SR RF and PM2222 ACCENT ST

Code Information: Serial Numbers: 2736872, 2736871, 2736870, 2736874, 2736873, 2538305, 2538304, 2538301, 2538306, 2538307, 2538302, 2512808, 2512812, 2512811, 2384089, 2512807, 2384108, 2384112, 2397881, 2393253, 2393254, 2401631, 2512803, 2401623, 2401617, 2512810, 2384086, 2384126, 2384101, 2384122, 2384121, 2384105, 2384096, 2384098, 2384116, 2384110, 2384111, 2384120, 2384082, 2384085, 2384123, 2384124, 2384107, 2384117, 2384087, 2384097, 2384077, 2393264, 2384115, 2384119, 2384114, 2384104, 2384100, 2384078, 2384092, 2384081, 2384084, 2397878, 2401620, 2384080, 2384079, 2384099, 2401621, 2401624, 2384083, 2512819, 2512818, 2401626, 2401622, 2397879, 2397872, 2393252, 2393259, 2401619, 2401618, 2401629, 2397874, 2397880, 2401628, 2384106, 2393255, 2393256, 2393257, 2512802, 2512805, 2512800, 2512817, 2512801, 2512804, 2512813, 2512814, 2512815, 2512816, 2512806, 2512809, 2384102, 2384095, 2384125, 2384113, 2384103, 2393262.