

FDA Home³ Medical Devices⁴ Databases⁵

Medical Device Recalls

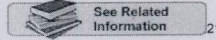


510(k)⁷ Registration & Listing⁸ Adverse Events⁹ Recalls¹⁰ PMA¹¹ Classification¹² Standards¹³ Inspections¹⁴ CFR Title 21¹⁵ Radiation-Emitting Products¹⁶ X-Ray Assembler¹⁷ Medsun Reports¹⁸ CLIA¹⁹ TPLC²⁰

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Class 1 Recall
Gemstar Infusion System



Date Posted November 21, 2013
Recall Status¹ Open
Recall Number Z-0349-2014
Premarket Notification 510(K) Number K060806²²
Product Classification Pump, Infusion²³ - Product Code FRN²⁴

Product The GemStar Pump is a small and lightweight, single channel infusion device designed for use in the home, in the hospital, or anywhere electronic infusion is required. The GemStar Pump can be powered by AC mains adaptor, rechargeable battery pack, docking station, or two disposable AA alkaline batteries. When powered by batteries, The GemStar Pump is ideal for ambulatory patients.

Code Information *** 1) List Number 13000, Serial Numbers: 98121336, 98121173, 98120835, 98120730, 98120768, 98120782, 98120788, 98120822, 98120824, 98120839, 98120856, 98120880, 98120885, 98120895, 98120915, 98120749, 98120769, 98120774, 98120784, 98120859, 98120884, 98121019, 98121066, 98121079, 98121083, 98121135, 98121153, 98121163, 98121197, 98120522, 98120653, 13431222, 98120635, 98120405, 98120508, 98120634, 98121147, 98120543, 12470380, 98120512, 98120815, 98120681, 97971490, 97970893, 97970240, 98070264, 98070295, 99170068, 99170032, 98070345, 98070476, 98070905, 98070995, 97972107, 97972609, 97971538, 98021653, 98021821, 99400401, 99400435, 97970456, 13431303, 98021816, 97972825, 98021121, 97971767, 99107521, 98020395, 14180727, 98120459, 98120495, 98120777, 98020964, 98070286, 98121157, 97972571, 97970541, 97971254, 98120535, 98120640, 98120840, 97970194, 98021636, 98020575, 97972639, 99222573, 98021550, 98021603, 98021682, 98370030, 98020523, 98020446, 98020441, 99107526, 97971754, 98020929, 98020932, 98022223, 13434785, 98020072, 98020317, 98021476, 98021478, 98021732, 98021891, 98021912, 98021252, 99170080, 98020623, 98020018, 98020293, 98020574, 98021031, 98021423, 98021449, 98020013, 97972018, 98021177, 98020264, 99221974, 98020817, 98021687, 98070125, 98021304, 98021546, 98022039, 98020281, 97972802, 97972086, 97971122, 12470492, 98121130, 97972659, 97972489, 98120869, 13433080, 97972047, 97972824, 98020549, 98021584, 97970313, 97970073, 98021364, 98020312, 98021961, 98020127, 98020606, 98021194, 99222658, 98020490, 98021141, 98021276, 98021171, 98020460, 98021969, 99107535, 99221815, 98021977, 98021120, 98021412, 99222620, 14180122, 99400456, 98071220, 98070607, 98070371, 98070781, 98070815, 98070696, 98070812, 97972981, 97970766, 98020074, 98020902, 14180174, 99219028, 98070190, 13433667, 97970613, 98021101, 98021099, 97970666, 97970308, 97970071, 98021367, 98021508, 98021308, 98021309, 98021208, 97972842, 97972841, 99222510, 98020727, 98020235, 98021264, 98021708, 98021794, 97971750, 99170302, 98070212, 98070006, 97972808, 98021554, 98021900, 99400482, 98020054, 98021195, 98021496, 98120534, 98020866, 98021179, 98070850, 98070448, 98070794, 97972040, 97971807, 98350110, 97971723, 98350105, 98350089, 98021587, 98021999, 98021207, 98021968, 98020855, 98021551, 99400235, 98070699, 97972950, 99222016, 98070351, 97971659, 98020901, 98020949, 98020474, 98021592, 98021932, 97971790, 97971766, 97972867, 97972283, 13432084, 99170140, 98070868, 98070028, 98070717, 98070296, 98070688, 99220393, 98121080, 12474733, 99222601, 97971952, 99222578, 98121160, 97970769, 97970839, 99222563, 99222322, 97970124, 97972801, 13430060, 14180300, 99221044, 97972664, 97970952, 97970873, 13430773, 97972475, 97972824, 13431359, 12471354, 99221849, 99221798, 98120493, 98120726, 98120696, 99222537, 99220861, 13432293, 13434708, 97970948, 14180791, 13433680, 13431566, 13431924, 99222636, 99222656, 12474581, 13433821, 12474354, 12471791, 13433340, 13432931, 13431284, 13440709, 13433382, 99221243, 13433983, 97971063, 97971874, 99222356, 99221852, 14180397, 13430576, 12474729, 13432281, 12473137, 13432245, 12470955, 13431610, 13436245, 99222612, 13434287, 12470279, 13433445, 13431619, 12473303, 12470403, 13431307, 98120382, 99222532, 13435380, 98020906, 12474665, 13430152, 99221958, 14180515, 99222578, 12473180, 13434080, 13439991, 97970460, 97970303, 13430198, 13430743, 13435220, 13438795, 13430039, 13432326, 13431725, 13431485, 13431224, 13433164, 99222614, 99222331, 13431989, 13432293, 13434726, 13431827, 13430627, 13431950, 13430182, 13434556, 12473423, 13436180, 13432449, 99222375, 13431069, 13430881, 97972801, 99222384, 13431420, 13432862, 13432588, 12474249, 13439388, 98021812, 99222471, 99222379, 13437386, 99222608, 99222423, 99221856, 13434243, 13433174, 13430135, 13433314, 12474465, 12473145, 13433684, 12471384, 14180622, 13440159, 99222418, 13431720, 12474332, 12471844, 13431992, 13439898, 13433072, 99222523, 13434042, 13432775, 99222578, 99220435, 13430344, 14180036, 13439887, 97970496, 97970510, 13431002, 13432432, 14180638, 13438445, 12471365, 98120641, 13432828, 99222539, 99220428, 12470727, 13431121, 13434646, 12472866, 13434339, 13433351, 13433021, 13433746, 13433597, 14180301, 13431965, 13433449, 99222633, 12470294, 99222348, 98021598, 12472916, 12472926, 12472854, 13431168, 98020252, 13432809, 12474227, 97970117, 13430007, 99222505, 13440463, 12471872, 13432893, 13430543, 14180874, 99222047, 14181058, 12470501, 12471513, 12474272, 13431727, 12474057, 99220921, 12471545, 98020372, 12470387, 13433411, 13433763, 12472231, 13434621, 13434369, 12471484, 13431471, 97972256,

