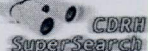


FDA Home³ Medical Devices⁴ Databases⁵

Medical Device Recalls

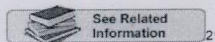


510(k)⁷ Registration & Listing⁸ Adverse Events⁹ Recalls¹⁰ PMA¹¹ Classification¹² Standards¹³ Inspections¹⁴ CFR Title 21¹⁵ Radiation-Emitting Products¹⁶ X-Ray Assembler¹⁷ Medsun Reports¹⁸ CLIA¹⁹ TPLC²⁰

New Search

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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,

For Additional Information Contact	Hospira Global Complaint Management 800-441-4100
Manufacturer Reason for Recall	The proximal and distal pressure sensor calibration can drift resulting in the pump failing the Proximal or Distal Occlusion Operational Test, as described in the GemStar Technical Service Manual, or reporting one of the following errors during device setup or infusion: 1) Cassette Check - D; 2) Cassette Check - P; 3) Proximal Occlusion; 4) Distal Occlusion; 5) Pressure Calibration Err
FDA Determined Cause ²	DESIGN: Device Design
Action	Hospira sent an Urgent Device Field Correction letter dated March 15, 2013, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. The letter asks that customers immediately perform proximal and distal occlusion tests as defined in the GemStar Technical Service Manual. If the device fails either of the tests, remove it from clinical service and contact Hospira at 1-800-441-4100 (Monday - Friday, 8:00 AM - 5:00 PM) to report the issue and arrange for the return of the device for recalibration. The letter further reminds customers that the proximal and distal occlusion tests should be performed on an annual basis as a part of the yearly GemStar maintenance schedule. Customers were also requested to complete and return the attached reply form and return it to Hospira by fax to 1-888-714-5077 or by e-mail to Hospira7906@stericycle.com. Customers were directed to notify their consignees if they further distributed the product and confirm they have done so by return of the reply form to Stericycle. For questions regarding this recall call 800-441-4100.
Quantity in Commerce	1) List Number 13000: 2,162 pumps; 2) List Number 13100: 15 pumps; 3) List Number 13150: 1,955 pumps
Distribution	Worldwide Distribution - USA including AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NM, NV, NY, OH, OK, OR, PA, RI, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY. Internationally to Australia, New Zealand, China, Hong Kong, Taiwan, Japan, Korea, Philippines, Thailand, Malaysia, Canada, Austria, Bahrain, Belgium, Croatia, Denmark, Egypt, Finland, France, Germany, Gibraltar, Greece, Hungary, Iceland, Ireland, Israel, Italy, Jordan, Kuwait, Lebanon, Libya, Luxembourg, Malta, Netherlands, Norway, Oman, Portugal, Qatar, Romania, Saudi Arabia, Slovenia, South Africa, Spain, Sweden, Switzerland, Turkey, UK, United Arab Emirates, Brazil, Chile and Colombia.
Total Product Life Cycle	TPLC Device Report²⁵

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁶](#)

² Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database • [510\(K\)s with Product Code = FRN and Original Applicant = HOSPIRA, INC.²⁷](#)

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