Class 1 Recall Puritan Bennett

See Related Information[22]

Date Posted	October 28, 2014
Recall Status[1]	Open
Recall Number	Z-0112-2015
Recall Event ID	69320[23]
Premarket Notification 510(K) Number	K131252[24]
Product Classification	Ventilator, Continuous, Facility Use[25] - **Product Code** CBK[26]
Product	Covidien Puritan Bennett 980 Ventilator, Rx ONLY. Suitable for service in a hospital (institutions) and intra-hospital transport to provide continuous positive pressure ventilator for Neonatal (NICU) through Adult patient populations.
Code Information	Model number PB980 Ventilator:35B1400143, 35B1400684, 35B1400627, 35B1400708, 35B1400398, 35B1400482, 35B1400491, 35B1400512, 35B1400601, 35B1400121, 35B1400568, 35B1400590, 35B1400595, 35B1400599, 35B1400606, 35B1400106, 35B1400146, 35B1400169, 35B1400226, 35B1400260, 35B1400270, 35B1400263, 35B1400351, 35B1400373, 35B1400400, 35B1400401, 35B1400608, 35B1400089, 35B1400112, 35B1400683, 35B1400685, 35B1400678, 35B1400118, 35B1400114, 35B1400355, 35B1400144, 35B1400300, 35B1400379, 35B1400412, 35B1400472, 35B1400489, 35B1400490, 35B1400492, 35B1400493, 35B1400499, 35B1400500, 35B1400501, 35B1400502, 35B1400507, 35B1400577, 35B1400207, 35B1400211, 35B1400216, 35B1400222, 35B1400225, 35B1400231, 35B1400267, 35B1400312, 35B1400323, 35B1400340, 35B1400383, 35B1400128, 35B1400363, 35B1400459, 35B1400589, 35B1400616, 35B1400637, 35B1400483, 35B1400311, 35B1400447, 35B1400648, 35B1400651, 35B1400654, 35B1400662, 35B1400686, 35B1400692, 35B1400175, 35B1400294, 35B1400436, 35B1400485, 35B1400586, 35B1400644, 35B1400687, 35B1400689, 35B1400694, 35B1400700, 35B1400661, 35B1400676, 35B1400693, 35B1400732, 35B1400734, 35B1400736, 35B1400737, 35B1400742, 35B1400280, 35B1400360, 35B1400471, 35B1400609, 35B1400674, 35B1400688, 35B1400755, 35B1400480, 35B1400675, 35B1400706, 35B1400771, 35B1400667, 35B1400704, 35B1400705, 35B1400727, 35B1400743, 35B1400279, 35B1400285, 35B1400262, 35B1400265, 35B1400259, 35B1400494, 35B1400403, 35B1400779, 35B1400783, 35B1400509, 35B1400724, 35B1400763, 35B1400767, 35B1400566, 35B1400768, 35B1400772, 35B1400791, 35B1400793, 35B1400817, 35B1400525, 35B1400796, 35B1400801, 35B1400809, 35B1400821, 35B1400828, 35B1400333, 35B1400366, 35B1400392, 35B1400440, 35B1400463, 35B1400478, 35B1400308, 35B1400347, 35B1400367, 35B1400396, 35B1400078, 35B1400099, 35B1400130, 35B1400155, 35B1400157, 35B1400158, 35B1400174, 35B1400176, 35B1400178, 35B1400180, 35B1400281, 35B1400315, 35B1400631, 35B1400635, 35B1400625, 35B1400653, 35B1400843, 35B1400847, 35B1400233, 35B1400271, 35B1400337, 35B1400350, 35B1400359, 35B1400368, 35B1400384, 35B1400468, 35B1400486, 35B1400495, 35B1400094, 35B1400236, 35B1400437, 35B1400438, 35B1400479, 35B1400496, 35B1400505, 35B1400506, 35B1400427, 35B1400511, 35B1400325, 35B1400462, 35B1400514, 35B1400536, 35B1400537, 35B1400544, 35B1400066, 35B1400200, 35B1400782, 35B1400829, 35B1400015, 35B1400110, 35B1400516, 35B1400517, 35B1400859, 35B1400013, 35B1400103, 35B1400167, 35B1400124, 35B1400007, 35B1400058, 35B1400083, 35B1400129, 35B1400132, 35B1400006, 35B1400079, 35B1400113, 35B1400116, 35B1400219, 35B1400163, and 35B1400543.
Recalling Firm/	Nellcor Puritan Bennett Inc. (dba Covidien LP)

Manufacturer	6135 Gunbarrel Ave Boulder, Colorado 80301-3214
Manufacturer Reason for Recall	A software issue may lead to ventilator inoperative situations.
FDA Determined Cause [2]	DESIGN: Software Design
Action	The firm sent Urgent: Field Correction Action letters, dated October 3, 2014, to consignees. The letter identified the affected product and the reason for the recall. Customers were provided actions to be taken, as well as, important safety reminders. The letter informed customers that they may continue to use their ventilators pending the software correction as long as two gas sources are connected to the ventilator at all times. Customers are to complete the attached acknowledgement and receipt form and fax it to Covidien at the number provided. For further assistance, customers are to contact the Technical Support Department at 1-800-255-6774.
Quantity in Commerce	324 units
Distribution	Worldwide Distribution -- USA, including the states of CA, CO, FL, GA, KY, MA, MN, NC, NY, OH, OK, PA, SC, TN, TX, UT, WI; and, the countries of Canada, Mexico, Saudi Arabia, South Africa, and United Arab Emirates.
Total Product Life Cycle	TPLC Device Report[27]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[28]
[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 = CBK and Original Applicant = COVIDIEN[29]

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm