GE Healthcare ventilator recall gets Class I status from the FDA

Mass Device

The FDA stamps GE Healthcare's Aestiva/5 7900 ventilator recall with Class I status, the most serious category.

GE Healthcare [1] (NYSE:GE [2]) landed Class I status for its Aestiva/5 7900 ventilator recall, a category the FDA reserves for the most serious issues "in which there is a reasonable probability that use of these products will cause serious adverse health consequences or death."

GE recalled the devices, which deliver continuous breathing support for patients who require mechanical ventilation during surgical procedures, over concerns that its 2 vaporizers may inappropriately deliver agents simultaneously.

That could result in over-delivery if both vaporizers contain the same agent or in simultaneous delivery of more than one agent, according to the recall notice [3].

Links:
[1] http://www.massdevice.com/company/ge-healthcare
[2] http://www.google.com/finance?q=ge
[3] http://www.fda.gov/MedicalDevices/Safety/RecallsCorrectionsRemovals/ListofRecalls/ucm311325.htm