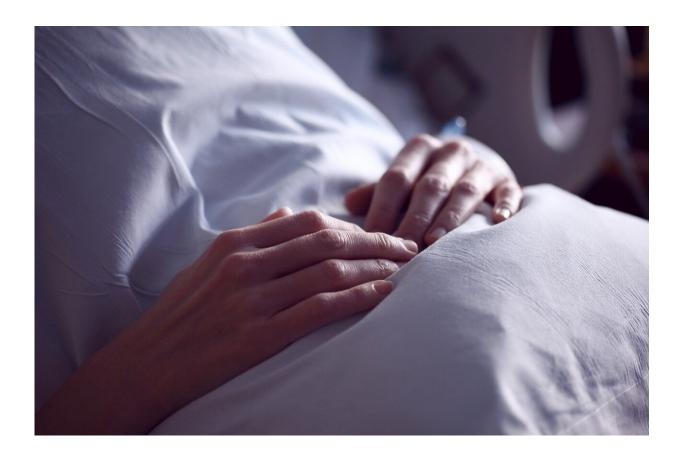


Optum joins FDA, manufacturer in recalling infusion pumps that killed one patient

May 31 2024, by Burl Gilyard, Star Tribune



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OptumHealth Care Solutions, a subsidiary of UnitedHealth Group, joined the manufacturer and the U.S. Food and Drug Administration in recalling an infusion pump system that has killed at least one patient.



Eden Prairie-based Optum's Nimbus II Plus infusion pumps—part of its homecare Infusion setup—is one of several similar products from Massachusetts-based InfuTronix in the Class 1 recall, the FDA's most serious because of the risk of serious injury or death. The infusion pump system delivers medications and fluids to a patient via IV or injections, including as a patient-controlled analgesia (PCA) for <u>pain management</u>.

InfuTronix previously recalled more than 52,000 pumps in February after reporting 3,698 complaints, six serious injuries and one death related to the pump issues.

Potential problems involved battery failure, drug leakage, incorrect flow rates and system errors. Those issues can cause <u>microbial contamination</u>, under-dosing that leads to dangerous changes in <u>blood pressure</u>, dehydration, seizures, shock and/or organ failure.

Optum reported no injuries or deaths beyond those identified in the InfuTronix recall. The Optum recall applies to 208 devices.

"We are committed to providing safe, convenient and affordable access to medical products for our patients," Optum said in a statement. "The device at issue is not originally manufactured by Optum, and we are complying with FDA requirements related to this matter. Optum has not had any report of injury from our patient population related to this device."

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Citation: Optum joins FDA, manufacturer in recalling infusion pumps that killed one patient (2024, May 31) retrieved 19 June 2024 from https://medicalxpress.com/news/2024-05-optum-fda-recalling-infusion-patient.html

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