



California Medical Device Recall Information



Recall Name

GE Healthcare Recalls Nuclear Medicine Systems Due to Risk of Serious Injury or Death

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|--------------|--|--|---|
| 06/13/13 | <ul style="list-style-type: none"> Infinia Nuclear Medicine Systems VG and VG Hawkeye Nuclear Medicine Systems Helix Nuclear Medicine Systems Brivo NM615 Discovery NM630 Optima NM/CT640 Discovery NM/CT670 | GE Healthcare, LLC Wauwatosa, WI | <p><i>A death was reported due to injuries sustained when a portion of an NM system fell on the patient during a scan.</i></p> <p><i>Serious injuries or death may result from the failure associated with this recall.</i></p> |
| Recall Class | Product Identification | Distribution | Affected Dates |
| I | <p>Affected Models (see Firm Notice):</p> <p><u>Infinia</u>: 3/8, II-3/8, VC, II-VC, 3/8-Hawkeye, VC-Hawkeye, II-3/8-Hawkeye, II-VC-Hawkeye, II-3/8-HE4, II-5/8-HE4, II-VC-HE4;</p> <p><u>VG and VG Hawkeye</u>: Varicam, Millennium VG 3/8, Millennium VG 5/8, Millennium VG 3/8 Hawkeye, Millennium VG 5/8 Hawkeye, Discovery VH;</p> <p><u>Helix Nuclear Medicine Systems</u>; <u>Brivo</u> NM615; <u>Discovery</u> NM630; <u>Optima</u> NM/CT640; <u>Discovery</u> NM/CT670</p> | CA, nationwide | <p>Distributed from:</p> <p>October 1992 to June 2013.</p> |

FOR ADDITIONAL INFORMATION, PLEASE VISIT:

<http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm362946.htm>