State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

# CALIFORNIA DEVICE RECALL INFORMATION SHEET

## Philips North America Recalls Brightview Gamma Camera For Component Failure Resulting In The Detector Unexpectedly Falling

| Recall Date | Product Description | Recalling Firm | Recall Reason |
|---|---|---|---|
| 2/7/2023 | **Brightview, Gamma Camera System**<br>Model Nos.: 6-digit format 882480; 12-digit format 453560279781 453560279791 453560279811 453560279801; 4x4 digit format 2170-3000A 2170-3001A 2170-3002A 2170-3003A | **PHILIPS NORTH AMERICA**<br>Cambridge, Massachusetts | Detector may unexpectedly fall due to component failure. If the detector is positioned below center of gantry, there is potential for abrasion, contusion, laceration, and/or fracture to patient's lower limbs, as well as interruption to normal system operation. If detector is positioned above center of gantry, there may be an interruption to normal system operation. |
| 2/7/2023 | **Brightview XCT, Gamma Camera For Spect**<br>Model Nos.: 6-digit format 882482;12-digit format 453560462131 453560749161 | **PHILIPS NORTH AMERICA**<br>Cambridge, Massachusetts | Detector may unexpectedly fall due to a component failure. If the detector is positioned below center of gantry, there is potential for abrasion, contusion, laceration, and/or fracture to patient's lower limbs, as well as interruption to normal system ope-ration. If detector is positioned above center of gantry, there may be interruption to normal system operation. |

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| 2/7/2023 | **Brightview X, Gamma Camera For Spect**<br>Model Nos.: 6-digit format 882478; 12-digit format 453560824741 453560829261 | **Philips North America**<br>Cambridge, Massachusetts | Detector may unexpectedly fall due to a component failure. If the detector is positioned below center of gantry, there is a potential for abrasion, contusion, laceration, and/or fracture to the patient's lower limbs, as well as an interruption to normal system operation. If detector is positioned above center of gantry, there may be an interruption to normal system operation. |

| Recall Class | Product Identification | Distribution | Affected Dates |
|---|---|---|---|
| I | **Brightview, Gamma Camera System**<br>All serial numbers are affected. No UDI-DI available for this product. | 302 Units Nationwide | December, 2023 and prior |
| I | **Brightview XCT, Gamma Camera For Spect**<br>All serial numbers are affected. No UDI-DI available for this product. | 106 Units Nationwide | December, 2023 and prior |
| I | **BrightView X, Gamma Camera For Spect**<br>All serial numbers are affected. No UDI-DI available for this product. | 56 Units Nationwide | December, 2023 and prior |

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE Brightview, BrightView XCT, BrightView X