State of California—Health and Human Services Agency

California Department of Public Health

Food and Drug Branch – Device Recalls

CALIFORNIA DEVICE RECALL INFORMATION SHEET

Olympus Corporation Recalls Olympus High-Flow Insufflation Unit for Over Insufflation of the Abdominal Cavity

Recall Date	Product Description	Recalling Firm	Recall Reason
10/25/2023	**Olympus High-Flow Insufflation Unit** Model UHI-4. For laparoscopic surgery.	**OLYMPUS CORPORATION OF THE AMERICAS** Center Valley, Pennsylvania	There have been reports of patients suffering arrhythmias, reported as short cardiac arrests, during surgical procedures where UHI-4s were used. These events may have been due to an over insufflation of the abdominal cavity resulting from use of the UHI-4 during the procedures.

Recall Class	Product Identification	Distribution	Affected Dates
I	**Olympus High-Flow Insufflation Unit** UDI-DI: 04953170324147; All Serial Numbers	3136 Units Nationwide including California	22 September 2023 and prior

FOR ADDITIONAL INFORMATION, PLEASE VISIT THE FDA WEBSITE