California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Olympus Corporation of the Americas Single Use Guide Sheath Kits

Recall Date	Product Description	Recalling Firm	Recall Reason
02/11/2025	Olympus Single Use Guide Sheath Kits with the following product descriptions and model numbers: Single Use Guide Sheath Kit K-201 2.0MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush; Model Number: K-201 Single Use Guide Sheath Kit K-202 2.0MM Channel Set: Guide Sheath, Biopsy Forceps; Model Number: K-202 Single Use Guide Sheath Kit K-203 2.6MM Channel Set: Guide Sheath, Biopsy Forceps, Cytology Brush; Model Number: K-203 Single Use Guide Sheath Kit K-204 2.6MM Channel Set: Guide Sheath, Biopsy Forceps; Model Number: K-204. Used to collect cells or tissue specimens in the respiratory organs.	Olympus Corporation of the Americas	Potential for the radiopaque tip of the guide sheath component to disassociate and fall off into the patient.

Recall Class	Product Identification	Distribution	Affected Dates
I	Model Number: K-201; UDI-DI: 04953170245466; All Lots. Model Number: K-202; UDI-DI: 04953170245480; All Lots Model Number: K-203; UDI-DI: 04953170245503; All Lots Model Number: K-204; UDI-DI: 04953170245527; All Lots	454 units nationwide	January and prior.

For additional information, please visit the FDA Website.