California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Olympus Corporation of the Americas Cystoscope Outer Sheath

Recall Date	Product Description	Recalling Firm	Recall Reason
11/08/2024	Brand Name: Olympus Product Name: Cystoscope Outer Sheath Model/Catalog Number: WA22810A Software Version: N/A Product Description: Outer sheaths can be combined with rigid Telescopes. Component: N/A	Olympus Corporation of the Americas	Olympus is removing the statement of compatibility with a GreenLight Laser for BPH therapy from the Instruction for Use (IFU) due to the potential for a damaged tip during use of a laser probe.

Recall Class	Product Identification	Distribution	Affected Dates
II	Model: WA22810A UDI: 04042761051729 Lot #: All lots	738 units nationwide including California.	September and prior.

For additional information, please visit the FDA Website.