California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Olympus Corporation of the Americas SOLTIVE Pro SuperPulsed Laser System
Model/Catalog Numbers: TFL-SLS, TFL-PLS

Recall Date	Product Description	Recalling Firm	Recall Reason
05/1/2025	Brand Name: Powered Laser Surgical Instrument Product Name: SOLTIVE Pro SuperPulsed Laser System Model/Catalog Numbers: TFL-SLS, TFL-PLS Product Description: SOLTIVE Laser Systems use technology to increase procedural efficiency and flexibility to ureteroscopy, PCNL, and potential soft tissue applications. Component: No	Olympus Corporation of the Americas	Preset treatment parameters are not consistently being used in accordance with the IFU.

Recall Class	Product Identification	Distribution	Affected Dates
II	SOLTIVE Pro SuperPulsed Laser System: UDI-DI: TFL-SLS - 00821925044135; TFL-PLS - 00821925044111 All units included Powered Laser Surgical Instrument - Laser module component information Name: TFL Premium Laser Unit, TFL Standard Laser Unit UDI-DI: TFL-CPLU - 00821925044586; TFL-CSLU - 00821925044593	91 Units	April 2025 and Prior

For additional information, please visit the FDA Website.