California Device Recall Information Sheet

Food and Drug Branch – Device Recalls

Straumann USA LLC TLX/TLC SP Guided Implant Drive

Recall Date	Product Description	Recalling Firm	Recall Reason
04/14/2025	TLX/TLC SP Guided Implant Driver, for ratchet, stainless steel; REF: 037.3002;	Straumann USA LLC	The devices are missing the laser marked depth markings.

Recall Class	Product Identification	Distribution	Affected Dates
II	REF: 037.3002; UDI-DI: 07630031750587; Packaging Lot number: LGMZ8, GLKJ9; Lot number engraved on part: HTXT5.	There was a single piece of Article 037.3002, Lot LGMZ8 distributed in California to Beacon Oral Specialists.	March 2025 and Prior

For additional information, please visit the FDA Website.