

K261221 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)

Jul 24, 2026
101 days to decision

K261221 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k261221/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Apr 14, 2026
Decision date	Jul 24, 2026
Days to decision	101 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	Dolan Mills
510(k) history	13 submissions · 13 cleared · 2012-2026

510k Database - www.510kdatabase.net
Device record: <https://www.510kdatabase.net/k261221/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated August 20, 2026