

K242191 SOLTIVE™ Laser System (SOLTIVE™ Pro SuperPulsed Laser, SOLTIVE™ Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)Aug 23, 2024
29 days to decisionK242191 · Product code: **GEX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k242191/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 25, 2024
Decision date	Aug 23, 2024
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Olympus Surgical Technologies America
Location	Southborough, MA, US
Contact	Apurva Joshi
510(k) history	12 submissions · 12 cleared · 2012-2024

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