

K211401 SOLTIVE Laser System (SOLTIVE Pro SuperPulsed Laser, SOLTIVE Premium SuperPulsed Laser, SOLTIVE Laser Fibers, and Accessories)Jun 3, 2021
28 days to decisionK211401 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k211401/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	May 6, 2021
Decision date	Jun 3, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Acmi, Inc.
Location	Westborough, MA, US
Contact	Julie Acker
Website	https://www.olympusmedical.com
510(k) history	42 submissions · 42 cleared · 2007-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211401/> 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 May 14, 2026