

K082407 MODIFICATION TO ULTRALIGHT II ND: YAG LASER SYSTEMFeb 3, 2009
166 days to decisionK082407 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k082407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 21, 2008
Decision date	Feb 3, 2009
Days to decision	166 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sandstone Medical Technologies, LLC
Location	Woodland, CA, US
Contact	MARK ROHRER
510(k) history	11 submissions · 11 cleared · 2004-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k082407/> 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 June 14, 2026