

K083900 ERBIUM FRACTIONAL HANDPIECEFeb 27, 2009
60 days to decisionK083900 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k083900/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 29, 2008
Decision date	Feb 27, 2009
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Palomar Medical Products, Inc.
Location	Cary, NC, US
Contact	Sharon Timberlake
510(k) history	21 submissions · 21 cleared · 1998-2011

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083900/> 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 18, 2026