

K052806 BURANEOct 17, 2005
13 days to decisionK052806 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k052806/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 4, 2005
Decision date	Oct 17, 2005
Days to decision	13 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Wavelight Laser Technologie AG
Location	North Reading, MA, US
Contact	ALEXANDER POPP
510(k) history	8 submissions · 8 cleared · 2004-2006

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k052806/> 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 July 1, 2026