

K973764 TEMPERATURE DIAGNOSTIC ACCESSORYDec 31, 1997
90 days to decisionK973764 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k973764/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Oct 2, 1997
Decision date	Dec 31, 1997
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	New Star Lasers, Inc.
Location	Auburn, CA, US
Contact	DAVE HENNINGS
510(k) history	29 submissions · 29 cleared · 1995-2014

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973764/> 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 6, 2026