

K992298 IRIDERM, MODEL APEX 800Dec 9, 1999
154 days to decisionK992298 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k992298/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 8, 1999
Decision date	Dec 9, 1999
Days to decision	154 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Iridex Corp
Location	Mountain View, CA, US
Contact	BRAD RENTON
510(k) history	13 submissions · 13 cleared · 1998-2012

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k992298/> 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 15, 2026