

**K080006 AFFIRM WITH XPL HANDPIECE AND ER:YAG LASER
MODULE**

Feb 28, 2008
57 days to decision

K080006 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k080006/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jan 2, 2008
Decision date	Feb 28, 2008
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cynosure, Inc.
Location	Bedford, MA, US
Contact	GEORGE CHO
510(k) history	98 submissions · 98 cleared · 1992-2019

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k080006/> 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