

**K946304 COHERENT FAMILY OF CO2 SURGICAL LASER
SCANNER HANDPIECES**

Mar 15, 1995
77 days to decision

K946304 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k946304/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Dec 28, 1994
Decision date	Mar 15, 1995
Days to decision	77 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Lumenis, Inc.
Location	Mchenry, IL, US
Contact	ANNE C WORDEN
510(k) history	43 submissions · 43 cleared · 1979-2022

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k946304/> 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 May 27, 2026