

K032357 NOVUS TTX LASER AND DELIVERY DEVICES WITH ACCESSORIESOct 9, 2003
71 days to decisionK032357 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k032357/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 30, 2003
Decision date	Oct 9, 2003
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k032357/>. 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