

K050453 ODYSSEY 2.4G, DENLASER ELITE, MODEL 002-00050May 27, 2005
94 days to decisionK050453 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k050453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 22, 2005
Decision date	May 27, 2005
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ivoclar Vivadent, Inc.
Location	Amherst, NY, US
Contact	DONNA HARNETT
Website	https://www.ivoclar.com
510(k) history	65 submissions · 65 cleared · 2001-2026

Ivoclar Vivadent, Inc. is a dental solutions provider based in Amherst, US. The company develops modern products for dental practitioners and laboratory technicians. The company has received FDA 510(k) clearances from total submissions since 2001. Dental devices represent 97% of its regulatory portfolio. The latest clearance was issued in 2026, confirming active market engagement. Recent cleared devices include restorative materials, adhesives, CAD-on restorations, bulk-fill composites, and curing lights. The product portfolio spans chairside and laboratory workflows for ...
