FDA 510(k) Premarket Notification

K062258 GENESIS DIODE LASER

CLEARED

Mar 21, 2007
229 days to decision

K062258 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k062258/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Aug 4, 2006
Decision date	Mar 21, 2007
Days to decision	229 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ivoclar Vivadent, Inc.**
Location	Amherst, NY, US
Contact	DONNA MARIE HARTNETT
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 ...