

K100558 QUANTA DIODE LASER SYSTEMJul 22, 2010
143 days to decisionK100558 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k100558/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 1, 2010
Decision date	Jul 22, 2010
Days to decision	143 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Quanta System Spa
Location	Chelmsford, MA, US
Contact	ISABELLA CARRER
510(k) history	57 submissions · 57 cleared · 2006-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k100558/> 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 20, 2026