

K090762 LEDAAug 28, 2009
158 days to decisionK090762 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k090762/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 23, 2009
Decision date	Aug 28, 2009
Days to decision	158 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	Quantel Derma GmbH
Location	Bozeman, MT, US
Contact	DIETMAR FISCHER
510(k) history	2 submissions · 2 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k090762/> 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 22, 2026