FDA 510(k) Premarket Notification

K090762 LEDA

CLEARED

Aug 28, 2009
158 days to decision

K090762 · Product code: **GEX** · General & Plastic Surgery
Source: 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