FDA 510(k) Premarket Notification

K250504 Leonardo Duster

CLEARED

Jul 14, 2025
144 days to decision

K250504 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250504/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Feb 20, 2025
Decision date	Jul 14, 2025
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ceramoptec GmbH**
Location	Bonn, DE
Contact	Roland Dreschau
510(k) history	2 submissions · 2 cleared · 2021-2025

REGULATORY CONSULTANT

Consulting firm	**Kamm & Associates**
Contact	Daniel Kamm

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov