FDA 510(k) Premarket Notification

K210951 Leonardo Mini Blue

CLEARED

Sep 1, 2021
155 days to decision

K210951 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210951/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Mar 30, 2021
Decision date	Sep 1, 2021
Days to decision	155 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