FDA 510(k) Premarket Notification

CLEARED

K201520 The Alma Opus System, Colibri Applicator and Tips

Oct 27, 2021
506 days to decision

K201520 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k201520/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 8, 2020
Decision date	Oct 27, 2021
Days to decision	506 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Alma Lasers, Inc.**
Location	Buffalo Grove, IL, US
Contact	Jessica Rivera-Montejo
510(k) history	19 submissions · 19 cleared · 2010-2025

REGULATORY CONSULTANT

Consulting firm	**Kathy Maynor Consulting**
Contact	Kathy Maynor

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