FDA 510(k) Premarket Notification

K222064 The Alma Soprano Titanium

CLEARED

Oct 12, 2022
91 days to decision

K222064 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Jul 13, 2022
Decision date	Oct 12, 2022
Days to decision	91 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