

K222064 The Alma Soprano TitaniumOct 12, 2022
91 days to decisionK222064 · 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](https://accessdata.fda.gov)

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