

K202953 Aurolase Therapy, Laser Delivery Device (LDD)Oct 3, 2022
733 days to decisionK202953 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k202953/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument (GEX)
Date received	Sep 30, 2020
Decision date	Oct 3, 2022
Days to decision	733 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Nanospectra Biosciences, Inc.
Location	Houston, TX, US
Contact	David Jordan
510(k) history	2 submissions · 2 cleared · 2022-2025

REGULATORY CONSULTANT

Consulting firm	Bentley Biomedical Consulting, LLC
Contact	Shepard G. Bentley

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k202953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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