

K243701 AuroLase® SystemJul 2, 2025
215 days to decisionK243701 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k243701/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Nov 29, 2024 |
| Decision date | Jul 2, 2025 |
| Days to decision | 215 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 Bentley |

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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