

K213105 Epilaser AbsoluteDec 13, 2022
445 days to decisionK213105 · Product code: **GEX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k213105/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Sep 24, 2021 |
| Decision date | Dec 13, 2022 |
| Days to decision | 445 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Epilady 2000, LLC |
| Location | Washington D.C., DC, US |
| Contact | Moshe Rosenthal |
| 510(k) history | 4 submissions · 4 cleared · 1994-2024 |

REGULATORY CONSULTANT

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|-----------------|-----------------------------|
| Consulting firm | Hogan Lovells US LLP |
| Contact | John J Smith |

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/k213105/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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