

**K133297 QUADROSTARPROGREEN,
QUADROSTARPROYELLOW**Jun 10, 2014
228 days to decisionK133297 · Product code: **GEX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k133297/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Oct 25, 2013 |
| Decision date | Jun 10, 2014 |
| Days to decision | 228 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Asclepion Laser Technologies GmbH |
| Location | Chelmsford, MA, US |
| Contact | ANTJE KATZER |
| Website | https://www.aclepion.com |
| 510(k) history | 29 submissions · 29 cleared · 2004-2026 |

Asclepion Laser Technologies GmbH is a leader in medical laser technology for aesthetic medicine and surgery. The company has operated since 1977 and serves customers in more than 70 countries. Asclepion maintains a manufacturing facility in Chelmsford, US, and specializes in innovative laser systems for dermatological and surgical applications. The company has received FDA 510(k) clearances from total submissions, with no denied submissions on record. 93% of submissions focus on General & Plastic Surgery devices, reflecting the company's core expertise in this category. ...

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k133297/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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