FDA 510(k) Premarket Notification

# K003765 LYRA G SERIES SURGICAL LASER SYSTEM (SL SERIES Q-SWITCHED ND:YAG CONFIGURATION)

**CLEARED**

Mar 6, 2001
90 days to decision

K003765 · Product code: **GEX** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k003765/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Powered Laser Surgical Instrument (GEX) |
| Date received | Dec 6, 2000 |
| Decision date | Mar 6, 2001 |
| Days to decision | 90 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Laserscope** |
| Location | Santa Clara, CA, US |
| Contact | PAUL H HARDMAN |
| 510(k) history | 60 submissions · 60 cleared · 1985-2006 |