

K100395 HARMONY VLED SURGICAL LIGHTNING SYSTEMMar 17, 2010
29 days to decisionK100395 · Product code: **FST** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k100395/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Light, Surgical, Fiberoptic (FST) |
| Date received | Feb 16, 2010 |
| Decision date | Mar 17, 2010 |
| Days to decision | 29 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | STERIS Corporation |
| Location | Mentor, OH, US |
| Contact | ROBERT SULLIVAN |
| 510(k) history | 204 submissions · 202 cleared · 1997-2026 |

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