

K081477 LUXTEC MLX LIGHT SOURCEJun 18, 2008
22 days to decisionK081477 · Product code: **FCW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k081477/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Light Source, Fiberoptic, Routine (FCW) |
| Date received | May 27, 2008 |
| Decision date | Jun 18, 2008 |
| Days to decision | 22 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Integra Luxtec, Inc. |
| Location | West Boylston, MA, US |
| Contact | RITA WADLEIGH |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008 |

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