

K153698 LumenR Tissue Retractor SystemApr 19, 2016
118 days to decisionK153698 · Product code: **ODB** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k153698/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Endoscopic Contamination Prevention Sheath (ODB) |
| Date received | Dec 23, 2015 |
| Decision date | Apr 19, 2016 |
| Days to decision | 118 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Lumenr, LLC |
| Location | Matawan, NJ, US |
| Contact | GREGORY PISKUN |
| 510(k) history | 1 submissions · 1 cleared · 2016-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153698/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 3, 2026