

K141622 ILLUMINATED MEDIASTINOSCOPEJan 9, 2015
206 days to decisionK141622 · Product code: **EWY** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k141622/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Mediastinoscope, Surgical (EWY) |
| Date received | Jun 17, 2014 |
| Decision date | Jan 9, 2015 |
| Days to decision | 206 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Aegis Surgical, Ltd. |
| Location | Holly Springs, NC, US |
| Contact | TAMMY CARREA |
| 510(k) history | 2 submissions · 2 cleared · 2015-2016 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k141622/> 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