

K163454 ECHELON FLEX 45mm Powered Plus Articulating Endoscopic Linear Cutters, ECHELON ENDOPATH Endoscopic Linear Cutter Reloads, 45mmJan 5, 2017
27 days to decisionK163454 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k163454/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Staple, Implantable (GDW) |
| Date received | Dec 9, 2016 |
| Decision date | Jan 5, 2017 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ethicon Endo-Surgery, LLC |
| Location | Blue Ash, OH, US |
| Contact | Carmen Ortiz |
| Website | https://www.jnjmedtech.com |
| 510(k) history | 69 submissions · 69 cleared · 2006-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k163454/> 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 2, 2026