

K161804 LigaSure Retractable L-Hook Laparoscopic Sealer/Divider

Sep 16, 2016
78 days to decisionK161804 · Product code: **GEI** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k161804/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Electrosurgical, Cutting & Coagulation & Accessories (GEI) |
| Date received | Jun 30, 2016 |
| Decision date | Sep 16, 2016 |
| Days to decision | 78 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien |
| Location | North Haven, CT, US |
| Contact | DAWN D. TINDALL |
| 510(k) history | 130 submissions · 126 cleared · 2008-2024 |

Covidien is an Irish-registered global healthcare products company headquartered in North Haven, Connecticut. Now part of Medtronic following a 2015 acquisition, the brand continues to operate as a major medical device manufacturer. Covidien maintains a strong FDA 510(k) regulatory record with cleared devices from total submissions spanning 2008 to 2024. The company specializes in General & Plastic Surgery devices, with a dominant focus on surgical staplers, sutures, and wound closure systems. Recent clearances include advanced stapling technologies, endotracheal tubes, a...

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