

**K123318 IDRIVE ULTRA POWERED HANDLE AND ENDO GIA
ADAPTER**Dec 18, 2012
54 days to decisionK123318 · Product code: **GDW** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k123318/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Staple, Implantable (GDW) |
| Date received | Oct 25, 2012 |
| Decision date | Dec 18, 2012 |
| Days to decision | 54 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Covidien, Formerly US Surgical A Divison of Tyco H |
| Location | North Haven, CT, US |
| Contact | SARAH RIZK |
| 510(k) history | 13 submissions · 13 cleared · 2010-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k123318/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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