

**K202701 GIA Stapler with Tri-Staple Technology**Dec 7, 2020  
82 days to decisionK202701 · Product code: **GDW** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k202701/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Special                            |
| Device classification | Staple, Implantable (GDW)          |
| Date received         | Sep 16, 2020                       |
| Decision date         | Dec 7, 2020                        |
| Days to decision      | 82 days                            |
| Third-party review    | No                                 |
| Combination product   | No                                 |
| PCCP authorized       | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Covidien</b>                           |
| Location       | North Haven, CT, US                       |
| Contact        | Leo Chen                                  |
| 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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