

**K151548 VersaOne Bladed Trocar, VersaOne Bladeless Trocar**Jul 2, 2015  
23 days to decisionK151548 · Product code: **GCJ** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k151548/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Special                                      |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received         | Jun 9, 2015                                  |
| Decision date         | Jul 2, 2015                                  |
| Days to decision      | 23 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---|
| Company        | <b>Covidien</b>                           |
| Location       | North Haven, CT, US                       |
| Contact        | Trang Huynh                               |
| 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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k151548/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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