

**K082619 SILS PORT, MODELS SILSPT5, SILSPT12**Nov 7, 2008  
59 days to decisionK082619 · Product code: **GCJ** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k082619/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Laparoscope, General & Plastic Surgery (GCJ) |
| Date received         | Sep 9, 2008                                  |
| Decision date         | Nov 7, 2008                                  |
| Days to decision      | 59 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|--|
| Company        | <b>Covidien Lp, Formerly Registered AS United States</b> |
| Location       | North Haven, CT, US                                      |
| Contact        | ROBERT ZOTT  |
| 510(k) history | 7 submissions · 7 cleared · 2008-2009                    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k082619/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 22, 2026