

**K123776 POLARIS 100/200**Mar 8, 2013  
88 days to decisionK123776 · Product code: **FTD** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k123776/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Abbreviated                        |
| Device classification | Lamp, Surgical (FTD)               |
| Date received         | Dec 10, 2012                       |
| Decision date         | Mar 8, 2013                        |
| Days to decision      | 88 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Drager Medical GmbH</b>            |
| Location       | Andover, MA, US                       |
| Contact        | BETH ZIS                              |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k123776/> 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 9, 2026