

**K083098 NAVIGATOR APPLICATIONS SUITE**Apr 1, 2009  
166 days to decisionK083098 · Product code: **BSZ** · Anesthesiology  
Source: <https://www.510kdatabase.net/k083098/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Gas-machine, Anesthesia (BSZ)      |
| Date received         | Oct 17, 2008                       |
| Decision date         | Apr 1, 2009                        |
| Days to decision      | 166 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>GE Healthcare Finland Oy</b>         |
| Location       | Madison, WI, US                         |
| Contact        | ADRIENNE LENZ                           |
| 510(k) history | 30 submissions · 30 cleared · 2007-2023 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083098/> 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 May 24, 2026