

**K851554 OVERSHOES (SURCHAUSSURES)**Apr 30, 1985  
14 days to decisionK851554 · Product code: **FXP** · General HospitalSource: <https://www.510kdatabase.net/k851554/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Cover, Shoe, Operating-room (FXP)  |
| Date received         | Apr 16, 1985                       |
| Decision date         | Apr 30, 1985                       |
| Days to decision      | 14 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Roseburg SA</b>                      |
| Location       | Washington, DC, US                      |
| Contact        | CHAMBORD                                |
| 510(k) history | 24 submissions · 23 cleared · 1985-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k851554/>; 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 22, 2026