

**K970537 REXTON MODEL 48 AND 49PP**Mar 28, 1997  
44 days to decisionK970537 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k970537/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received         | Feb 12, 1997                                    |
| Decision date         | Mar 28, 1997                                    |
| Days to decision      | 44 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Rexton, Inc.</b>                     |
| Location       | Mchenry, IL, US                         |
| Contact        | DANIEL L ANDERSON                       |
| 510(k) history | 21 submissions · 21 cleared · 1983-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970537/> 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 July 5, 2026