

**K972818 D72 DIGITAL**Oct 17, 1997  
80 days to decisionK972818 · Product code: **ESD** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k972818/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)              |
| Submission type       | Traditional                                     |
| Device classification | Hearing Aid, Air-conduction, Prescription (ESD) |
| Date received         | Jul 29, 1997                                    |
| Decision date         | Oct 17, 1997                                    |
| Days to decision      | 80 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement                                       |

**APPLICANT**

---

|                |   |
|----------------|---|
| Company        | <b>Philips Hearing Instruments Co.</b>  |
| Location       | Mahwah, NJ, US                          |
| Contact        | TED MIKSIEWICZ                          |
| 510(k) history | 20 submissions · 20 cleared · 1991-1997 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972818/> 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