

**K972543 TWIST PPAGC-1, TWIST PP**Jul 23, 1997  
14 days to decisionK972543 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k972543/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Jul 9, 1997
Decision date	Jul 23, 1997
Days to decision	14 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Trutone</b>
Location	Tulsa, OK, US
Contact	ZIAD SHWIYAT
510(k) history	5 submissions · 5 cleared · 1997-1998

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972543/> 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