

**K964245 PRECISE, TYNMPANETTE, AND XACTO IMPRESSION KITS**Feb 4, 1997  
103 days to decisionK964245 · Product code: **ESD** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k964245/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hearing Aid, Air-conduction, Prescription (ESD)
Date received	Oct 24, 1996
Decision date	Feb 4, 1997
Days to decision	103 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Starkey Laboratories, Inc.</b>
Location	Mchenry, IL, US
Contact	SHARI L SWIDEN
510(k) history	60 submissions · 60 cleared · 1977-2020

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k964245/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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