

**K972815 PARTIAL/TOTAL/POROUS POLYETHYLENE  
OSSICULAR REPLACEMENT**Oct 8, 1997  
72 days to decisionK972815 · Product code: **ETB** · Ear, Nose, Throat  
Source: <https://www.510kdatabase.net/k972815/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Jul 28, 1997
Decision date	Oct 8, 1997
Days to decision	72 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Grace Medical, Inc.</b>
Location	Memphis, TN, US
Contact	ANTHONY D PRESCOTT
510(k) history	14 submissions · 14 cleared · 1994-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k972815/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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