

K991394 STAPES PROSTHESESMay 18, 1999
27 days to decisionK991394 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k991394/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Apr 21, 1999
Decision date	May 18, 1999
Days to decision	27 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991394/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026