

K002737 SMITH & NEPHEW PORPS & TORPSOct 12, 2000
41 days to decisionK002737 · Product code: **ETB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k002737/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Sep 1, 2000
Decision date	Oct 12, 2000
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gyrus Ent LLC
Location	Bartlett, TN, US
Contact	ALICIA FARAGE
510(k) history	28 submissions · 28 cleared · 1997-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k002737/> 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 June 30, 2026