

K002464 SMITH & NEPHEW OFF-CENTERED PORPAug 29, 2000
19 days to decisionK002464 · Product code: **ETB** · Ear, Nose, ThroatSource: <https://www.510kdatabase.net/k002464/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Aug 10, 2000
Decision date	Aug 29, 2000
Days to decision	19 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

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