

K962564 RICHARDS TOTAL/PARTIAL PROSTHESISJan 22, 1997
205 days to decisionK962564 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k962564/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Jul 1, 1996
Decision date	Jan 22, 1997
Days to decision	205 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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