

K950885 HAPEX MALLEABLE PORPMar 15, 1995
15 days to decisionK950885 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k950885/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Feb 28, 1995
Decision date	Mar 15, 1995
Days to decision	15 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Smith & Nephew Richards, Inc.
Location	Memphus, TN, US
Contact	RONALD K SMITH
510(k) history	87 submissions · 72 cleared · 1990-1997

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