

K964909 ESTERM MALLEUS TOTAL AND PARTIAL MIDDLE EAR PROSTHESIS

Mar 10, 1997
91 days to decision

K964909 · Product code: **ETB** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k964909/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Prosthesis, Partial Ossicular Replacement (ETB)
Date received	Dec 9, 1996
Decision date	Mar 10, 1997
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Xomed, Inc.
Location	Arnold, MO, US
Contact	DAVID TIMLIN
510(k) history	82 submissions · 81 cleared · 1976-2000

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k964909/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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