FDA 510(k) Premarket Notification

K232059 Tympanostomy Tubes

CLEARED

Nov 24, 2023
136 days to decision

K232059 · Product code: **ETD** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k232059/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tube, Tympanostomy (ETD)
Date received	Jul 11, 2023
Decision date	Nov 24, 2023
Days to decision	136 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Grace Medical, Inc.**
Location	Memphis, TN, US
Contact	Mark Melton
510(k) history	14 submissions · 14 cleared · 1994-2023