FDA 510(k) Premarket Notification

K030791 ANMP (ACOUSTIC NEURO MODULATION PROTOCOL)

CLEARED

Apr 17, 2003
36 days to decision

K030791 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k030791/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Mar 12, 2003
Decision date	Apr 17, 2003
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Tinnitech, Ltd.**
Location	Sydney, AU
Contact	LACHLAN JAMES
510(k) history	1 submissions · 1 cleared · 2003-2003