FDA 510(k) Premarket Notification

K073636 TINNITUS SOUND GENERATOR MODULE

CLEARED

Mar 13, 2008
78 days to decision

K073636 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k073636/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Dec 26, 2007
Decision date	Mar 13, 2008
Days to decision	78 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Gn Resound A/S**
Location	Ballerup, DK
Contact	LARS HAGANDER
510(k) history	3 submissions · 3 cleared · 2008-2015