FDA 510(k) Premarket Notification

K150171 Tinnitus Sound Generator Module

CLEARED

May 14, 2015
108 days to decision

K150171 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k150171/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Masker, Tinnitus (KLW)
Date received	Jan 26, 2015
Decision date	May 14, 2015
Days to decision	108 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