FDA 510(k) Premarket Notification

K221125 SilentCloud

CLEARED

Jan 4, 2023
261 days to decision

K221125 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k221125/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Apr 18, 2022
Decision date	Jan 4, 2023
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Aureliym GmbH**
Location	Bad Neuenahr-Ahrweiler, DE
Contact	Markus Haller
510(k) history	1 submissions · 1 cleared · 2023-2023