FDA 510(k) Premarket Notification

K080955 ZEN PROGRAM (MIND 440 HEARING AID)

CLEARED

Jun 27, 2008
85 days to decision

K080955 · Product code: **KLW** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k080955/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Masker, Tinnitus (KLW)
Date received	Apr 3, 2008
Decision date	Jun 27, 2008
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Widex Hearing Aid Co., Inc.**
Location	Mchenry, IL, US
Contact	FRANCIS KUK
510(k) history	52 submissions · 52 cleared · 1976-2008