FDA 510(k) Premarket Notification

K083597 SONOWAND INVITE

CLEARED

Sep 25, 2009
294 days to decision

K083597 · Product code: **HAW** · Neurology
Source: https://www.510kdatabase.net/k083597/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Dec 5, 2008
Decision date	Sep 25, 2009
Days to decision	294 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Sonowand AS**
Location	Ne, MN, US
Contact	CONSTANCE G BUNDY
510(k) history	2 submissions · 2 cleared · 2009-2012