FDA 510(k) Premarket Notification

K080060 VIVOSONIC NEUROSCREEN

CLEARED

Apr 4, 2008
86 days to decision

K080060 · Product code: **GWJ** · Neurology
Source: https://www.510kdatabase.net/k080060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Auditory, Evoked Response (GWJ)
Date received	Jan 9, 2008
Decision date	Apr 4, 2008
Days to decision	86 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Vivosonic, Inc.**
Location	Stamford, CT, US
Contact	AMJAD RANA
510(k) history	5 submissions · 5 cleared · 2001-2024