FDA 510(k) Premarket Notification

K090866 NEUROCALM MODEL 1 AND 2

CLEARED

Oct 21, 2009
204 days to decision

K090866 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k090866/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Mar 31, 2009
Decision date	Oct 21, 2009
Days to decision	204 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Neuromed Devices, Inc.**
Location	Laguna Niguel, CA, US
Contact	ROBERT SEIPLE
510(k) history	1 submissions · 1 cleared · 2009-2009