FDA 510(k) Premarket Notification

K083030 TENS-EMS-14

CLEARED

Feb 5, 2009
118 days to decision

K083030 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k083030/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Oct 10, 2008
Decision date	Feb 5, 2009
Days to decision	118 days
Third-party review	Yes
Summary / Statement	Summary

APPLICANT

Company	**Emsi**
Location	Alexandria, VA, US
Contact	CHERITA JAMES
510(k) history	6 submissions · 6 cleared · 2008-2014