

**K991397 TRANSCUTANEOUS ELECTRICAL NERVE
STIMULATOR SE-30 TENS**Feb 11, 2000
296 days to decisionK991397 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k991397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Apr 21, 1999
Decision date	Feb 11, 2000
Days to decision	296 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sein Electronics Co., Ltd.
Location	Mahwah, NJ, US
Contact	S.H. HWANG
510(k) history	12 submissions · 12 cleared · 1991-2005

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