

K963507 EXTRA TENS (RI-2500) NEO TENS (RI-2000E)Mar 19, 1997
197 days to decisionK963507 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k963507/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Sep 3, 1996
Decision date	Mar 19, 1997
Days to decision	197 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Comtek Intl., Corp.
Location	Commack, NY, US
Contact	PING TSUNG HUAN
510(k) history	1 submissions · 1 cleared · 1997-1997

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