FDA 510(k) Premarket Notification

K961809 SHE-LI TENS STIMULATOR MODEL SL-101 RX

CLEARED

Feb 26, 1997
292 days to decision

K961809 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k961809/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	May 10, 1996
Decision date	Feb 26, 1997
Days to decision	292 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medi Consultants, Inc.**
Location	Paterson, NJ, US
Contact	SAUL LISS
510(k) history	1 submissions · 1 cleared · 1997-1997