FDA 510(k) Premarket Notification

K961050 RELIEFBAND TENS UNIT (MODIFICATION)

CLEARED

Aug 1, 1997
540 days to decision

K961050 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k961050/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Feb 8, 1996
Decision date	Aug 1, 1997
Days to decision	540 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Maven Labs, Inc.**
Location	Sacramento, CA, US
Contact	DANIEL J MANELLI
510(k) history	2 submissions · 2 cleared · 1991-1997