FDA 510(k) Premarket Notification

K821523 OMNI TENS

CLEARED

Jun 16, 1982
26 days to decision

K821523 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k821523/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	May 21, 1982
Decision date	Jun 16, 1982
Days to decision	26 days
Third-party review	No

APPLICANT

Company	**Omni Intl., Inc.**
Location	Walker, MI, US
510(k) history	12 submissions · 12 cleared · 1982-1999