FDA 510(k) Premarket Notification

K881424 PREMIER 10S (TENS)

CLEARED

Apr 11, 1988
6 days to decision

K881424 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k881424/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Apr 5, 1988
Decision date	Apr 11, 1988
Days to decision	6 days
Third-party review	No

APPLICANT

Company	**American Imex**
Location	Irvine, CA, US
Contact	JOAN FONG
510(k) history	11 submissions · 11 cleared · 1986-2004