FDA 510(k) Premarket Notification

K883188 T.E.N.S. UNIT SIGMA & TX-3

CLEARED

Dec 16, 1988
141 days to decision

K883188 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k883188/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jul 28, 1988
Decision date	Dec 16, 1988
Days to decision	141 days
Third-party review	No

APPLICANT

Company	**Diamond Medical Equipment, Inc.**
Location	Jamaica, NY, US
Contact	HARVEY DIAMOND
510(k) history	3 submissions · 3 cleared · 1988-1991