FDA 510(k) Premarket Notification

CLEARED

K965187 SPECTRUM II, SPECTRUM PLUS, AND SPECTRUM MAX-SD

Aug 1, 1997
220 days to decision

K965187 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k965187/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Dec 24, 1996
Decision date	Aug 1, 1997
Days to decision	220 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Sparta Surgical Corp.**
Location	Hayward, CA, US
Contact	THOMAS J BOUCHARD
510(k) history	7 submissions · 6 cleared · 1989-1997