FDA 510(k) Premarket Notification

K061166 DEEPWAVE PERCUTANEOUS NEUROMODULATION PAIN THERAPY SYSTEM

CLEARED

Aug 15, 2006
110 days to decision

K061166 · Product code: **NHI** · Neurology
Source: https://www.510kdatabase.net/k061166/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Electrical, Percutaneous (pens), For Pain Relief (NHI)
Date received	Apr 27, 2006
Decision date	Aug 15, 2006
Days to decision	110 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Biowave Corporation**
Location	North Attleboro, MA, US
Contact	MARY MCNAMARA-CULLINANE
510(k) history	7 submissions · 7 cleared · 2005-2021