FDA 510(k) Premarket Notification

K980892 HAKOMED ELECDT / PRO ELEDT SERIES

CLEARED

May 11, 1998
63 days to decision

K980892 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k980892/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Mar 9, 1998
Decision date	May 11, 1998
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Alive, Inc.**
Location	Honolulu, HI, US
Contact	KAI HANSJURGENS
510(k) history	2 submissions · 2 cleared · 1998-1998