FDA 510(k) Premarket Notification

K030998 MEDRELIEF SE SERIES, MODELS SE-50, SE-100, SE-200, SE-300

CLEARED

Oct 10, 2003
193 days to decision

K030998 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k030998/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Mar 31, 2003
Decision date	Oct 10, 2003
Days to decision	193 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Healthonics, Inc.**
Location	Rockville, MD, US
Contact	JAMES W KRONBERG
510(k) history	3 submissions · 3 cleared · 2001-2006