FDA 510(k) Premarket Notification

K120922 GUARDIAN DYSPHAGIA DUAL CHANNEL NMES UNIT

CLEARED

Feb 7, 2013
317 days to decision

K120922 · Product code: **IPF** · Physical Medicine
Source: https://www.510kdatabase.net/k120922/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Stimulator, Muscle, Powered (IPF)
Date received	Mar 27, 2012
Decision date	Feb 7, 2013
Days to decision	317 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Selectivemed Components, Inc.**
Location	Mt. Vernon, OH, US
Contact	DANIEL KAMM
510(k) history	7 submissions · 7 cleared · 1995-2013