FDA 510(k) Premarket Notification

K062284 CES ULTRA

CLEARED

Apr 5, 2007
241 days to decision

K062284 · Product code: **QJQ** · Neurology
Source: https://www.510kdatabase.net/k062284/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cranial Electrotherapy Stimulator To Treat Insomnia And/or Anxiety (QJQ)
Date received	Aug 7, 2006
Decision date	Apr 5, 2007
Days to decision	241 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Neuro-Fitness, LLC**
Location	Snoqualmie, WA, US
Contact	MICHAEL STEVENS
510(k) history	1 submissions · 1 cleared · 2007-2007

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k062284/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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