FDA 510(k) Premarket Notification

K162392 Avazzia

CLEARED

May 12, 2017
259 days to decision

K162392 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k162392/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH)
Date received	Aug 26, 2016
Decision date	May 12, 2017
Days to decision	259 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Avazzia, Inc.**
Location	Dallas, TX, US
Contact	TAMMY LAHUTSKY
510(k) history	4 submissions · 4 cleared · 2007-2021