FDA 510(k) Premarket Notification

K092292 CHECKPOINT

CLEARED

Oct 28, 2009
91 days to decision

K092292 · Product code: **ETN** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k092292/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve (ETN)
Date received	Jul 29, 2009
Decision date	Oct 28, 2009
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Ndi Medical, LLC**
Location	Cleveland, OH, US
Contact	JULIE GRILL
510(k) history	3 submissions · 3 cleared · 2006-2015