

K150005 Checkpoint, Checkpoint Head & NeckFeb 19, 2015
48 days to decisionK150005 · Product code: **ETN** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k150005/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve (ETN)
Date received	Jan 2, 2015
Decision date	Feb 19, 2015
Days to decision	48 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150005/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 5, 2026