

**K212355 Checkpoint Guardian Intraoperative Lead, Medium,
Checkpoint Guardian Intraoperative Lead, Large**Aug 26, 2021
28 days to decision

K212355 · Product code: ETN · Ear, Nose, Throat

Source: <https://www.510kdatabase.net/k212355/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve (ETN)
Date received	Jul 29, 2021
Decision date	Aug 26, 2021
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Checkpoint Surgical
Location	Cleveland, OH, US
Contact	Ben Cottrill
510(k) history	1 submissions · 1 cleared · 2021-2021

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