

K232991 BT-1000Aug 28, 2024
341 days to decisionK232991 · Product code: **QGL** · Neurology
Source: <https://www.510kdatabase.net/k232991/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Transcutaneous Nerve Stimulator For Adhd (QGL)
Date received	Sep 22, 2023
Decision date	Aug 28, 2024
Days to decision	341 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bistos Co., Ltd.
Location	Flintville, TN, US
Contact	Goeun Choi
510(k) history	11 submissions · 11 cleared · 2005-2025

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