

K231708 Axoguard HA+ Nerve Protector (AGHA12)Oct 12, 2023
122 days to decisionK231708 · Product code: **JXI** · Neurology
Source: <https://www.510kdatabase.net/k231708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cuff, Nerve (JXI)
Date received	Jun 12, 2023
Decision date	Oct 12, 2023
Days to decision	122 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Axoguard HA+ Nerve Protector (AGHA22); Axoguard HA+ Nerve Protector (AGHA24); Axoguard HA+ Nerve Protector (AGHA36); Axoguard HA+ Nerve Protector (AGHA48)

APPLICANT

Company	Axogen Corporation
Location	Alachua, FL, US
Contact	Shravani Shastry
510(k) history	3 submissions · 3 cleared · 2017-2023

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