

K200984 Guardian Needle ElectrodeMay 27, 2020
43 days to decisionK200984 · Product code: **GXZ** · Neurology
Source: <https://www.510kdatabase.net/k200984/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Needle (GXZ)
Date received	Apr 14, 2020
Decision date	May 27, 2020
Days to decision	43 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Rhythmink International, LLC
Location	Cayce, SC, US
Contact	Gabriel Orsinger
510(k) history	18 submissions · 18 cleared · 2002-2021

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