

**K241160 CAIs Sensor (CAIs-001)**Dec 13, 2024  
231 days to decisionK241160 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k241160/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Apr 26, 2024
Decision date	Dec 13, 2024
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Brainu Co., Ltd.</b>
Location	Seongnam-Si, KR
Contact	Sangwoo Choi
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>CTI Co., Ltd.</b>
Contact	Yeonwoo Lee

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k241160/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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