

K243788 IceCap product lineMar 13, 2025
94 days to decisionK243788 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k243788/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Dec 9, 2024
Decision date	Mar 13, 2025
Days to decision	94 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Bioserenity Medical Devices Group
Location	Paris, FR
Contact	Melanie Renaud-Samiri
510(k) history	1 submissions · 1 cleared · 2025-2025

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k243788/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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