

K260453 Remote Wave Electrode (AE03-50)Mar 12, 2026
29 days to decisionK260453 · Product code: **GXY** · Physical MedicineSource: <https://www.510kdatabase.net/k260453/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrode, Cutaneous (GXY)
Date received	Feb 11, 2026
Decision date	Mar 12, 2026
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Remote Wave Electrode (AE03-60)

APPLICANT

Company	Bionit Labs Srl
Location	Soleto, IT
Contact	Aventaggiato Matteo
510(k) history	2 submissions · 2 cleared · 2025-2026

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