

**K222863 Garment Electrodes**Feb 1, 2023  
132 days to decisionK222863 · Product code: **GXY** · Neurology  
Source: <https://www.510kdatabase.net/k222863/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 22, 2022
Decision date	Feb 1, 2023
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Tone-A-Matic International, Inc.</b>
Location	Mississauga, Ontario, CA
Contact	Manuel Chuck
510(k) history	4 submissions · 4 cleared · 2013-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222863/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026