FDA 510(k) Premarket Notification

K252439 Tutamen Self Adhesive Electrodes

CLEARED

May 1, 2026
270 days to decision

K252439 · Product code: **GXY** · Neurology
Source: https://www.510kdatabase.net/k252439/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 4, 2025
Decision date	May 1, 2026
Days to decision	270 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Dongguan Tutamen Metalwork Co., Ltd.**
Location	Dongguan, CN
Contact	Stephen Prior
510(k) history	2 submissions · 2 cleared · 2024-2026

REGULATORY CONSULTANT

Consulting firm	**Medical Devices Pathway, LLC**
Contact	Caitlyn Dzhafarov

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