

K201431 OGYILI TENS/NMES StimulatorNov 9, 2020
161 days to decisionK201431 · Product code: **GZJ** · Neurology
Source: <https://www.510kdatabase.net/k201431/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jun 1, 2020
Decision date	Nov 9, 2020
Days to decision	161 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Gongguan Tutamen Metalwork Co., Ltd.
Location	Dongguan, CN
Contact	Charles Shen
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	Manton Business and Technology Services
Contact	Charles Shen

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

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