

**K092546 GMDASZ TENS ELECTRODES, MODELS CWN1005,
DIA. 5CM, DWN2505, 5CMX5CM, CWN1007.DIA. 7CM,
CWN2509,5CMX9CM**

Dec 18, 2009
121 days to decision

K092546 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k092546/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Aug 19, 2009
Decision date	Dec 18, 2009
Days to decision	121 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Gmdasz Manufacturing Co., Ltd.
Location	Echo, OR, US
Contact	CHARLIE MACK
510(k) history	2 submissions · 2 cleared · 2009-2016

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Device record: <https://www.510kdatabase.net/k092546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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