

**K232995 Neurological Therapy Devices - Accessories:
Electrotherapy device Electrode belt for Abdominal Muscle
Trainer Toning, AC1001, AC1002, AC1003, AC1003, AC1004,
AC1005**

Jan 11, 2024
111 days to decision

K232995 · Product code: **GXY** · Neurology
Source: <https://www.510kdatabase.net/k232995/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrode, Cutaneous (GXY)
Date received	Sep 22, 2023
Decision date	Jan 11, 2024
Days to decision	111 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Electrotherapy device Electrode belt for back of body, AC2001, AC2002, AC2003, AC2004; Electrotherapy device Electrode belt for Body joints, AC3001, AC3008, AC3009, AC3010, AC3011; Electrotherapy device Electrode for Knee, AC3002, AC3004, AC3006; Electrotherapy device Electrode for Elbow, AC3003, AC3005, AC3007; Electrothe

APPLICANT

Company	Shenzhen Roundwhale Technology Co. , Ltd.
Location	Shenzhen, CN
Contact	Zeng Chunming
510(k) history	7 submissions · 7 cleared · 2018-2024

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Device record: <https://www.510kdatabase.net/k232995/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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