

K211055 Microcurrent device (Model: HBR2-1)Nov 5, 2021
210 days to decisionK211055 · Product code: **NFO** · Neurology
Source: <https://www.510kdatabase.net/k211055/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Transcutaneous Electrical, Aesthetic Purposes (NFO)
Date received	Apr 9, 2021
Decision date	Nov 5, 2021
Days to decision	210 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Shenzhen DJ Medical Equipment Co., Ltd.
Location	Shenzhen, CN
Contact	Jet Li
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	Guangzhou Keda Biology Technology Co, Ltd.
Contact	Jet Li

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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