FDA 510(k) Premarket Notification

K210202 BioWaveGO RX

CLEARED

Feb 24, 2021
30 days to decision

K210202 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k210202/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ)
Date received	Jan 25, 2021
Decision date	Feb 24, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Biowave Corporation**
Location	North Attleboro, MA, US
Contact	Bradford Siff
510(k) history	7 submissions · 7 cleared · 2005-2021

REGULATORY CONSULTANT

Consulting firm	**Mcra, LLC**
Contact	Dave McGurl

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