FDA 510(k) Premarket Notification

# K180943 BioWaveGO

**CLEARED**

Aug 17, 2018
129 days to decision

K180943 · Product code: **GZJ** · Neurology
Source: https://www.510kdatabase.net/k180943/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, For Pain Relief (GZJ) |
| Date received | Apr 10, 2018 |
| Decision date | Aug 17, 2018 |
| Days to decision | 129 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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