FDA 510(k) Premarket Notification

# K131921 ELECTRONIC PULSE STIMULATOR

**CLEARED**

Nov 15, 2013
142 days to decision

K131921 · Product code: **NUH** · Neurology
Source: https://www.510kdatabase.net/k131921/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Stimulator, Nerve, Transcutaneous, Over-the-counter (NUH) |
| Date received | Jun 26, 2013 |
| Decision date | Nov 15, 2013 |
| Days to decision | 142 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Shenzhen Jingkehui Electronic Co.., Ltd.** |
| Location | Mountain View, CA, US |
| Contact | BILL DAI |
| 510(k) history | 3 submissions · 3 cleared · 2013-2015 |