FDA 510(k) Premarket Notification

# K181107 Elevo® Kit Snoring Intervention Device

**CLEARED**

Dec 6, 2018
224 days to decision

K181107 · Product code: **LRK** · Ear, Nose, Throat
Source: https://www.510kdatabase.net/k181107/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Apr 26, 2018 |
| Decision date | Dec 6, 2018 |
| Days to decision | 224 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Zelegent, Inc.** |
| Location | Irvine, CA, US |
| Contact | David C. Humbert |
| 510(k) history | 2 submissions · 2 cleared · 2018-2022 |