FDA 510(k) Premarket Notification

# K220330 Soundly Anti Snoring Device

**CLEARED**

Sep 8, 2022
216 days to decision

K220330 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k220330/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Abbreviated |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Feb 4, 2022 |
| Decision date | Sep 8, 2022 |
| Days to decision | 216 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Greystone Ip, Ltd.** |
| Location | Belfast, IE |
| Contact | Judy Purvis |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |