FDA 510(k) Premarket Notification

# K210636 Morpheus

**CLEARED**

Feb 15, 2022
361 days to decision

K210636 · Product code: **LRK** · Dental
Source: https://www.510kdatabase.net/k210636/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Anti-snoring (LRK) |
| Date received | Feb 19, 2021 |
| Decision date | Feb 15, 2022 |
| Days to decision | 361 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Statement |

## APPLICANT

| | |
|---|---|
| Company | **S4S UK , Ltd.** |
| Location | Sheffield, GB |
| Contact | Matthew Everatt |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |