

K111293 SOUNDCURE SERENADE TINNITUS TREATMENT SYSTEMAug 24, 2011
110 days to decisionK111293 · Product code: **KLW** · Ear, Nose, Throat
Source: <https://www.510kdatabase.net/k111293/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Masker, Tinnitus (KLW) |
| Date received | May 6, 2011 |
| Decision date | Aug 24, 2011 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Soundcure, Inc. |
| Location | San Jose, CA, US |
| Contact | NANCY LINCE |
| 510(k) history | 2 submissions · 2 cleared · 2011-2015 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111293/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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