

K182847 Hudson RCI Voldyne Volumetric ExerciserJul 1, 2019
265 days to decisionK182847 · Product code: **BWF** · Anesthesiology
Source: <https://www.510kdatabase.net/k182847/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Spirometer, Therapeutic (incentive) (BWF) |
| Date received | Oct 9, 2018 |
| Decision date | Jul 1, 2019 |
| Days to decision | 265 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Teleflexmedical, Inc. |
| Location | Jeffrey, NH, US |
| Contact | Sirisha Kommana |
| 510(k) history | 64 submissions · 61 cleared · 1985-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k182847/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026