

K191541 Vave Personal Ultrasound SystemJul 10, 2019
29 days to decisionK191541 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k191541/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Jun 11, 2019 |
| Decision date | Jul 10, 2019 |
| Days to decision | 29 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vave Health, Inc. |
| Location | San Mateo, CA, US |
| Contact | Joseph Ko |
| 510(k) history | 2 submissions · 2 cleared · 2019-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191541/> 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 26, 2026