

K211746 Pocket Ultrasound SystemFeb 18, 2022
256 days to decisionK211746 · Product code: IYN · Radiology
Source: <https://www.510kdatabase.net/k211746/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received | Jun 7, 2021 |
| Decision date | Feb 18, 2022 |
| Days to decision | 256 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Guangdong Youkey Medical Co., Ltd. |
| Location | Foshan, CN |
| Contact | Hu Zeyi |
| 510(k) history | 2 submissions · 2 cleared · 2022-2024 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k211746/> 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 27, 2026