

K150580 UltraVision 2 Diagnostic Ultrasound SystemApr 7, 2015
29 days to decisionK150580 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k150580/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Mar 9, 2015 |
| Decision date | Apr 7, 2015 |
| Days to decision | 29 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Winprobe Corporation |
| Location | Palm Beach Gardens, FL, US |
| Contact | ROSE MALCHOW |
| 510(k) history | 2 submissions · 2 cleared · 2015-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k150580/> 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 16, 2026