

K172356 BladderScan Prime PLUS SystemSep 15, 2017
43 days to decisionK172356 · Product code: **IYO** · Radiology
Source: <https://www.510kdatabase.net/k172356/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received | Aug 3, 2017 |
| Decision date | Sep 15, 2017 |
| Days to decision | 43 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Verathon Incorporated |
| Location | Bothell, WA, US |
| Contact | Swapna Chirala |
| 510(k) history | 5 submissions · 5 cleared · 2007-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k172356/> 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