

K181666 Smart OneAug 1, 2018
37 days to decisionK181666 · Product code: **BZH** · Anesthesiology
Source: <https://www.510kdatabase.net/k181666/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Meter, Peak Flow, Spirometry (BZH) |
| Date received | Jun 25, 2018 |
| Decision date | Aug 1, 2018 |
| Days to decision | 37 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Mir Medical International Research |
| Location | Roma, IT |
| Contact | Gerda Van Houts |
| 510(k) history | 1 submissions · 1 cleared · 2018-2018 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181666/> 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 24, 2026