

K895963 MODIFIED STAR CALCMar 16, 1990
156 days to decisionK895963 · Product code: **BZC** · Anesthesiology
Source: <https://www.510kdatabase.net/k895963/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calculator, Pulmonary Function Data (BZC) |
| Date received | Oct 11, 1989 |
| Decision date | Mar 16, 1990 |
| Days to decision | 156 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Infrasonics Corp. |
| Location | Walker, MI, US |
| Contact | JIM HITCHIN |
| 510(k) history | 20 submissions · 19 cleared · 1984-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895963/>; 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