

K972309 JM-102 JAUNDICE METERSep 22, 1998
459 days to decisionK972309 · Product code: **MQM** · Chemistry
Source: <https://www.510kdatabase.net/k972309/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Bilirubin (total And Unbound) In The Neonate Test System (MQM) |
| Date received | Jun 20, 1997 |
| Decision date | Sep 22, 1998 |
| Days to decision | 459 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Air-Shields, Inc. |
| Location | Mchenry, IL, US |
| Contact | T. WHIT ATHEY |
| 510(k) history | 33 submissions · 33 cleared · 1976-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k972309/> 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 22, 2026