

K854278 NEG COMBO BREAKPOINT PANEL POS COMBOMar 4, 1986
131 days to decisionK854278 · Product code: **JWX** · Microbiology
Source: <https://www.510kdatabase.net/k854278/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Kit, Screening, Staphylococcus Aureus (JWX) |
| Date received | Oct 24, 1985 |
| Decision date | Mar 4, 1986 |
| Days to decision | 131 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | American Micro Scan |
| Location | Mchenry, IL, US |
| Contact | KRISTA L UNDERWOOD |
| 510(k) history | 24 submissions · 24 cleared · 1983-1987 |

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