

K964689 TRACCELL 2000 SLIDE MAPPING SYSTEMAug 18, 1997
269 days to decisionK964689 · Product code: **JOY** · Hematology
Source: <https://www.510kdatabase.net/k964689/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Automated Cell-locating (JOY) |
| Date received | Nov 22, 1996 |
| Decision date | Aug 18, 1997 |
| Days to decision | 269 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Accumed Intl., Inc. |
| Location | Westlake, OH, US |
| Contact | JOHN MIERS |
| 510(k) history | 12 submissions · 12 cleared · 1996-1999 |

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