

K933086 AFSC HEMO CONTROL #5331, AA2 HEMO CONTROL #5328

Oct 31, 1994
495 days to decision

K933086 · Product code: **JCM** · Hematology
Source: <https://www.510kdatabase.net/k933086/>

SUBMISSION DETAILS

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Control, Hemoglobin, Abnormal (JCM) |
| Date received | Jun 23, 1993 |
| Decision date | Oct 31, 1994 |
| Days to decision | 495 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Helena Laboratories |
| Location | Mchenry, IL, US |
| Contact | PAT FRANKS |
| 510(k) history | 280 submissions · 280 cleared · 1978-2013 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k933086/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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