

K911625 AMES DCA 2000TM ANALYZER AND REAGENT SYSTEMSep 5, 1991
147 days to decisionK911625 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k911625/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Apr 11, 1991 |
| Decision date | Sep 5, 1991 |
| Days to decision | 147 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Heraeus Kulzer, Inc. |
| Location | Elkhart, IN, US |
| Contact | ROSANNE M SAVOL |
| 510(k) history | 145 submissions · 145 cleared · 1988-2009 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k911625/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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