

K842328 AMER. HISTO-ID SYS PRIMARY LAMBDA CHAINAug 3, 1984
51 days to decisionK842328 · Product code: **DEH** · Immunology
Source: <https://www.510kdatabase.net/k842328/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Lambda, Antigen, Antiserum, Control (DEH) |
| Date received | Jun 13, 1984 |
| Decision date | Aug 3, 1984 |
| Days to decision | 51 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|--|
| Company | Bartels Immunodiagnostic Supplies, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 35 submissions · 34 cleared · 1981-1986 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k842328/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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