

K913614 FRUCTOSAMINE ABG21 TEST SYSTEMDec 2, 1991
111 days to decisionK913614 · Product code: **LCP** · Hematology
Source: <https://www.510kdatabase.net/k913614/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Glycosylated Hemoglobin (LCP) |
| Date received | Aug 13, 1991 |
| Decision date | Dec 2, 1991 |
| Days to decision | 111 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Boehringer Mannheim Corp. |
| Location | Mchenry, IL, US |
| Contact | JOHN D STEVENS |
| 510(k) history | 340 submissions · 340 cleared · 1976-1999 |

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