

K983176 ELECSYS MYOGLOBIN STAT ASSAYSep 24, 1998
14 days to decisionK983176 · Product code: **DDR** · Immunology
Source: <https://www.510kdatabase.net/k983176/>**SUBMISSION DETAILS**

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| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Myoglobin, Antigen, Antiserum, Control (DDR) |
| Date received | Sep 10, 1998 |
| Decision date | Sep 24, 1998 |
| Days to decision | 14 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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