

K803015 HEMESPEC IIDec 30, 1980
32 days to decisionK803015 · Product code: **GKR** · Hematology
Source: <https://www.510kdatabase.net/k803015/>**SUBMISSION DETAILS**

| | |
|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Hemoglobin, Automated (GKR) |
| Date received | Nov 28, 1980 |
| Decision date | Dec 30, 1980 |
| Days to decision | 32 days |
| Third-party review | No |

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k803015/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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