FDA 510(k) Premarket Notification

# K820573 HELENA HEMOGLOBIN DETECT COLUMN SYS

**CLEARED**

Apr 1, 1982
30 days to decision

K820573 · Product code: **GKA** · Hematology
Source: https://www.510kdatabase.net/k820573/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Abnormal Hemoglobin Quantitation (GKA) |
| Date received | Mar 2, 1982 |
| Decision date | Apr 1, 1982 |
| Days to decision | 30 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/k820573/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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