FDA 510(k) Premarket Notification

# K812226 HELENA HBF QUIPLATE CONTROL

**CLEARED**

Sep 1, 1981
22 days to decision

K812226 · Product code: **KQI** · Hematology
Source: https://www.510kdatabase.net/k812226/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Assay, Fetal Hemoglobin (KQI) |
| Date received | Aug 10, 1981 |
| Decision date | Sep 1, 1981 |
| Days to decision | 22 days |
| Third-party review | No |

## APPLICANT

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