FDA 510(k) Premarket Notification

# K842368 SICKLE CELL REAGENT SET

**CLEARED**

Jul 20, 1984
35 days to decision

K842368 · Product code: **GHM** · Hematology
Source: https://www.510kdatabase.net/k842368/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Sickle Cell (GHM) |
| Date received | Jun 15, 1984 |
| Decision date | Jul 20, 1984 |
| Days to decision | 35 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Livonia Diagnostics, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 16 submissions · 16 cleared · 1984-1985 |