FDA 510(k) Premarket Notification

# K920001 HEMOLAB SILIMAT REAGENT

**CLEARED**

Sep 25, 1992
267 days to decision

K920001 · Product code: **GFI** · Hematology
Source: https://www.510kdatabase.net/k920001/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Osteotome, Manual (GFI) |
| Date received | Jan 2, 1992 |
| Decision date | Sep 25, 1992 |
| Days to decision | 267 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Biomerieux Vitek, Inc.** |
| Location | Hazelwood, MO, US |
| Contact | DAVID K.BROADWAY |
| 510(k) history | 49 submissions · 49 cleared · 1992-1998 |