FDA 510(k) Premarket Notification

# K003812 VACUETTE SPEEDY QUICK-RELEASE HOLDER

**CLEARED**

Apr 30, 2001
140 days to decision

K003812 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k003812/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | Dec 11, 2000 |
| Decision date | Apr 30, 2001 |
| Days to decision | 140 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Greiner Vacuette North America, Inc.** |
| Location | Ellicott City, MD, US |
| Contact | Judi Smith |
| 510(k) history | 5 submissions · 5 cleared · 2000-2002 |