FDA 510(k) Premarket Notification

# K801108 DOUBLE ENDED VENTED TRANSFER DEVICE

**CLEARED**

May 30, 1980
21 days to decision

K801108 · Product code: **FMI** · General Hospital
Source: https://www.510kdatabase.net/k801108/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Hypodermic, Single Lumen (FMI) |
| Date received | May 9, 1980 |
| Decision date | May 30, 1980 |
| Days to decision | 21 days |
| Third-party review | No |

## APPLICANT

| | |
|---|---|
| Company | **Burron Medical Products, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 41 submissions · 40 cleared · 1979-1987 |