FDA 510(k) Premarket Notification

# K080303 EZ REGULAR

**CLEARED**

Aug 5, 2008
182 days to decision

K080303 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k080303/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Feb 5, 2008 |
| Decision date | Aug 5, 2008 |
| Days to decision | 182 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Meinntech Co., Ltd.** |
| Location | Deer Field, IL, US |
| Contact | DANIEL KAMM |
| 510(k) history | 1 submissions · 1 cleared · 2008-2008 |