FDA 510(k) Premarket Notification

**CLEARED**

# K181870 Infusion Sets with Precision Filter for Single Use, Precision Infusion Filter for Single Use, Extended Infusion Sets for Single Use

Feb 26, 2019
229 days to decision

K181870 · Product code: **FPA** · General Hospital
Source: https://www.510kdatabase.net/k181870/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, Administration, Intravascular (FPA) |
| Date received | Jul 12, 2018 |
| Decision date | Feb 26, 2019 |
| Days to decision | 229 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Wuhan W.E.O Science & Technology Development Co., Ltd.** |
| Location | Wuhun, CN |
| Contact | Chengling Fu |
| 510(k) history | 1 submissions · 1 cleared · 2019-2019 |

## REGULATORY CONSULTANT

| | |
|---|---|
| Consulting firm | **Mid-Link Consulting Co, Ltd.** |
| Contact | Diana Hong |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov