

K181814 AMSure Pre-filled Syringe for Balloon Inflation with Sterile WaterSep 4, 2018
57 days to decisionK181814 · Product code: **EZL** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181814/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Retention Type, Balloon (EZL) |
| Date received | Jul 9, 2018 |
| Decision date | Sep 4, 2018 |
| Days to decision | 57 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Amsino International, Inc. |
| Location | Ontario, CA, US |
| Contact | Cathy Hong |
| 510(k) history | 27 submissions · 27 cleared · 2002-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k181814/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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