FDA 510(k) Premarket Notification

# K172631 Arisure Dry Spike

**CLEARED**

Sep 29, 2017
28 days to decision

K172631 · Product code: **LHI** · General Hospital
Source: https://www.510kdatabase.net/k172631/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Set, I.v. Fluid Transfer (LHI) |
| Date received | Sep 1, 2017 |
| Decision date | Sep 29, 2017 |
| Days to decision | 28 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

## APPLICANT

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|---|---|
| Company | **Yukon Medical** |
| Location | Durham, NC, US |
| Contact | Todd Korogi |
| 510(k) history | 3 submissions · 3 cleared · 2017-2017 |