FDA 510(k) Premarket Notification

# K171081 Guider Catheter Introducer

**CLEARED**

May 9, 2017
28 days to decision

K171081 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k171081/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Apr 11, 2017 |
| Decision date | May 9, 2017 |
| Days to decision | 28 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Rhythm Xience, Inc. (Rxi)** |
| Location | Eden Prairie, MN, US |
| Contact | James Hassett |
| 510(k) history | 2 submissions · 2 cleared · 2017-2017 |