FDA 510(k) Premarket Notification

# K151981 Turnpike catheter

**CLEARED**

Aug 13, 2015
27 days to decision

K151981 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k151981/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Jul 17, 2015 |
| Decision date | Aug 13, 2015 |
| Days to decision | 27 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Vascular Solution, Inc.** |
| Location | Maple Grove, MN, US |
| Contact | BEKA VITE |
| 510(k) history | 1 submissions · 1 cleared · 2015-2015 |