

K063372 RADIFOCUS GLIDEWIRE ADVANTAGEJan 19, 2007
72 days to decisionK063372 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k063372/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Nov 8, 2006 |
| Decision date | Jan 19, 2007 |
| Days to decision | 72 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Terumo Medical Corp. |
| Location | Elkton, MD, US |
| Contact | MARK UNTERREINER |
| 510(k) history | 143 submissions · 143 cleared · 1980-2011 |

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