

K961445 RADIFOCUS GLIDEWIRE FOR CORONARY USE WITH PLATINUM (OR GOLD) COILJul 9, 1996
84 days to decisionK961445 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k961445/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Apr 16, 1996 |
| Decision date | Jul 9, 1996 |
| Days to decision | 84 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k961445/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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