

**K971281 RAULERSON ONE-STEP GUIDEWIRE INSERTION
BULB NEEDLE**Oct 9, 1997
185 days to decisionK971281 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k971281/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Apr 7, 1997 |
| Decision date | Oct 9, 1997 |
| Days to decision | 185 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Medcomp |
| Location | Mchenry, IL, US |
| Contact | JEANNE M CUSH |
| 510(k) history | 40 submissions · 34 cleared · 1982-2014 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k971281/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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