

**K071196 DISPOSABLE HIGH PRESSURE INJECTION LINES
WITH AND WITHOUT ROTATING ADAPTERS**Sep 6, 2007
129 days to decisionK071196 · Product code: **DQO** · Cardiovascular
Source: <https://www.510kdatabase.net/k071196/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Intravascular, Diagnostic (DQO) |
| Date received | Apr 30, 2007 |
| Decision date | Sep 6, 2007 |
| Days to decision | 129 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Coeur, Inc. |
| Location | Lebanon, TN, US |
| Contact | DEBRA F MANNING |
| 510(k) history | 14 submissions · 14 cleared · 2005-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k071196/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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