

K101011 HI-TORQUE BALANCE MIDDLEWEIGHT UNIVERSALMay 24, 2010
42 days to decisionK101011 · Product code: **DQX** · Cardiovascular
Source: <https://www.510kdatabase.net/k101011/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Wire, Guide, Catheter (DQX) |
| Date received | Apr 12, 2010 |
| Decision date | May 24, 2010 |
| Days to decision | 42 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Abbott Vascular, Inc. |
| Location | Redwood, CA, US |
| Contact | KAY SETZER |
| 510(k) history | 20 submissions · 17 cleared · 2000-2014 |

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