

K101615 POWERWIRE RADIOFREQUENCY GUIDEWIREJul 28, 2010
49 days to decisionK101615 · Product code: **PDU** · Cardiovascular
Source: <https://www.510kdatabase.net/k101615/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter For Crossing Total Occlusions (PDU) |
| Date received | Jun 9, 2010 |
| Decision date | Jul 28, 2010 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Baylis Medical Co., Inc. |
| Location | Mississauga, CA |
| Contact | MEGHAL KHAKHAR |
| 510(k) history | 28 submissions · 28 cleared · 1998-2013 |

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