

K151141 Cronus HP - High Pressure Peripheral Balloon CatheterJan 14, 2016
260 days to decisionK151141 · Product code: LIT · Cardiovascular
Source: <https://www.510kdatabase.net/k151141/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Angioplasty, Peripheral, Transluminal (LIT) |
| Date received | Apr 29, 2015 |
| Decision date | Jan 14, 2016 |
| Days to decision | 260 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Nipro Medical Corporation |
| Location | Lexington, KY, US |
| Contact | JESSICA OSWALD-MCLEOD |
| 510(k) history | 34 submissions · 34 cleared · 2005-2026 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151141/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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