

K081680 NUCLEUS-X, MODEL 230XJul 10, 2008
23 days to decisionK081680 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k081680/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Jun 17, 2008 |
| Decision date | Jul 10, 2008 |
| Days to decision | 23 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | NuMED, Inc. |
| Location | Hopkinton, NY, US |
| Contact | NICHELLE LAFLESH |
| 510(k) history | 49 submissions · 47 cleared · 1985-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081680/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026