FDA 510(k) Premarket Notification

# K081680 NUCLEUS-X, MODEL 230X

**CLEARED**

Jul 10, 2008
23 days to decision

K081680 · 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 |