

K042537 SUBMARINE PLUS PERCUTANEOUS TRANSLUMINAL ANGIOPLASTY (PTA) CATHETER, MODEL SUVXXXXXXXXXX

Nov 8, 2004
49 days to decision

K042537 · Product code: **DQY** · Cardiovascular
Source: <https://www.510kdatabase.net/k042537/>

SUBMISSION DETAILS

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Sep 20, 2004 |
| Decision date | Nov 8, 2004 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Invatec Innovative Technologies |
| Location | Plymouth, MN, US |
| Contact | MIKE WINEGAR |
| 510(k) history | 3 submissions · 3 cleared · 2004-2006 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k042537/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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