FDA 510(k) Premarket Notification

# K042624 AMPHIRION DEEP 0.014 OTW PTA BALLOON CATHETER

**CLEARED**

Jan 10, 2005
105 days to decision

K042624 · Product code: **DQY** · Cardiovascular
Source: https://www.510kdatabase.net/k042624/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Percutaneous (DQY) |
| Date received | Sep 27, 2004 |
| Decision date | Jan 10, 2005 |
| Days to decision | 105 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Invatec Innovative Technologies, S.R.L.** |
| Location | Plymouth, MN, US |
| Contact | MIKE WINEGAR |
| 510(k) history | 7 submissions · 7 cleared · 2005-2009 |

**510k Database** - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k042624/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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