

**K041727 MODIFICATION TO ATLANTIS PV IMAGING
CATHETER, MODEL 36456**Jul 23, 2004
28 days to decisionK041727 · Product code: **OBJ** · Cardiovascular
Source: <https://www.510kdatabase.net/k041727/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Catheter, Ultrasound, Intravascular (OBJ) |
| Date received | Jun 25, 2004 |
| Decision date | Jul 23, 2004 |
| Days to decision | 28 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Boston Scientific Scimed, Inc. |
| Location | Plymouth, MN, US |
| Contact | ROBERT Z PHILLIPS |
| 510(k) history | 35 submissions · 26 cleared · 1994-2004 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k041727/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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