FDA 510(k) Premarket Notification

# K813355 MODIFICATION OF THE PERCUTAN-BALLOON

**CLEARED**

Jul 2, 1982
217 days to decision

K813355 · Product code: **DSP** · Cardiovascular
Source: https://www.510kdatabase.net/k813355/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Balloon, Intra-aortic And Control (DSP) |
| Date received | Nov 27, 1981 |
| Decision date | Jul 2, 1982 |
| Days to decision | 217 days |
| Third-party review | No |

## APPLICANT

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|---|---|
| Company | **Smec, Inc.** |
| Location | Mchenry, IL, US |
| 510(k) history | 7 submissions · 7 cleared · 1980-1985 |