

**K885179 INTRO-FLEX SHEATH INTRODUCER W/AMC
THROMBOSHIELD**Aug 9, 1989
238 days to decisionK885179 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k885179/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Dec 14, 1988 |
| Decision date | Aug 9, 1989 |
| Days to decision | 238 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Baxter Healthcare Corp |
| Location | Mchenry, IL, US |
| Contact | CORRINE M TAFLINGER |
| 510(k) history | 505 submissions · 496 cleared · 1977-2019 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k885179/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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