

K990975 IN-LINE HEMOSTASIS VALVEMar 15, 2000
358 days to decisionK990975 · Product code: **DYB** · Cardiovascular
Source: <https://www.510kdatabase.net/k990975/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Introducer, Catheter (DYB) |
| Date received | Mar 23, 1999 |
| Decision date | Mar 15, 2000 |
| Days to decision | 358 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Merit Medical Systems, Inc. |
| Location | South Jordan, UT, US |
| Contact | CHESTER MCCOY |
| Website | https://www.merit.com |
| 510(k) history | 178 submissions · 170 cleared · 1988-2026 |

Merit Medical Systems, Inc. is a leading manufacturer of disposable medical devices for interventional, diagnostic, and therapeutic procedures. Based in South Jordan, the company serves hospitals and physicians worldwide. Merit Medical has established a strong FDA 510(k) regulatory record since its first clearance in 1988. The company has received FDA 510(k) clearances from total submissions. Recent clearances span cardiovascular devices, neurology, gastroenterology, and general surgery, demonstrating broad clinical expertise. The latest clearance in 2026 confirms the com...

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