FDA 510(k) Premarket Notification

# K240261 Siege Vascular Plug (SVP2.5-0.021)

**CLEARED**

May 2, 2024
92 days to decision

K240261 · Product code: **KRD** · Cardiovascular
Source: https://www.510kdatabase.net/k240261/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Vascular, For Promoting Embolization (KRD) |
| Date received | Jan 31, 2024 |
| Decision date | May 2, 2024 |
| Days to decision | 92 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |
| Other names | Siege Vascular Plug (SVP4-0.021); Siege Vascular Plug (SVP6-0.027) |

## APPLICANT

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|---|---|
| Company | **Merit Medical Systems, Inc.** |
| Location | South Jordan, UT, US |
| Contact | James Kenny |
| Website | https://www.merit.com |
| 510(k) history | 177 submissions · 169 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...

## REGULATORY CONSULTANT

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|---|---|
| Consulting firm | **Merit Medical Ireland, Ltd.** |
| Contact | James Kenny |

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov