

**K233813 Bearing nsPVA Express™**

Dec 21, 2023  
21 days to decision

K233813 · Product code: **NAJ** · Obstetrics & Gynecology  
Source: <https://www.510kdatabase.net/k233813/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	Nov 30, 2023
Decision date	Dec 21, 2023
Days to decision	21 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Merit Medical Systems, Inc.</b>
Location	South Jordan, UT, US
Contact	Mark Mullaney
Website	<a href="https://www.merit.com">https://www.merit.com</a>
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	<b>Biosphere Medical, S.A.</b>
Contact	Yves Wong

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

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