

K130259 BEARING NSPVA EMBOLIZATION PARTICLESJun 7, 2013
126 days to decisionK130259 · Product code: **NAJ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k130259/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	Feb 1, 2013
Decision date	Jun 7, 2013
Days to decision	126 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Merit Medical Systems, Inc.
Location	South Jordan, UT, US
Contact	LINDA VARROSO
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...
