

**K081768 COOK INCORPORATED POLYVINYL ALCOHOL FOAM
EMBOLIZATION PARTICLES**Dec 23, 2008
186 days to decisionK081768 · Product code: **NAJ** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k081768/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agents, Embolic, For Treatment Of Uterine Fibroids (NAJ)
Date received	Jun 20, 2008
Decision date	Dec 23, 2008
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Cook Incorporated
Location	Bloomington, IN, US
Contact	SUSANNE GALIN
510(k) history	175 submissions · 153 cleared · 2006-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k081768/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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