

K243799 Fetal PillowAug 29, 2025
261 days to decisionK243799 · Product code: **PWB** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k243799/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fetal Head Elevator (PWB)
Date received	Dec 11, 2024
Decision date	Aug 29, 2025
Days to decision	261 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	CooperSurgical, Inc.
Location	Mountain View, CA, US
Contact	Irina Fedorov
510(k) history	41 submissions · 40 cleared · 1991-2025

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