

K250438 CooperSurgical Milex® PessariesApr 11, 2025
56 days to decisionK250438 · Product code: **HHW** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k250438/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pessary, Vaginal (HHW)
Date received	Feb 14, 2025
Decision date	Apr 11, 2025
Days to decision	56 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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