FDA 510(k) Premarket Notification

K260380 Mendit

CLEARED

Mar 4, 2026
27 days to decision

K260380 · Product code: **PBQ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k260380/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Feb 5, 2026
Decision date	Mar 4, 2026
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Escala Medical, Ltd.**
Location	Misgav, IL
Contact	Edit Goldberg
510(k) history	1 submissions · 1 cleared · 2026-2026

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Lina Kontos

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

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Device record: https://www.510kdatabase.net/k260380/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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