

**K230730 Apyx**Jul 25, 2023  
131 days to decisionK230730 · Product code: **PBQ** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k230730/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Mar 16, 2023
Decision date	Jul 25, 2023
Days to decision	131 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Escala Medical</b>
Location	Misgav Industrial Park, IL
Contact	Edit Goldberg
510(k) history	2 submissions · 2 cleared · 2022-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells</b>
Contact	Lina Kontos

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

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