FDA 510(k) Premarket Notification

K213783 Apyx

CLEARED

Apr 5, 2022
123 days to decision

K213783 · Product code: **PBQ** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k213783/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fixation, Non-absorbable Or Absorbable, For Pelvic Use (PBQ)
Date received	Dec 3, 2021
Decision date	Apr 5, 2022
Days to decision	123 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells**
Contact	Jonathan Kahan

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