FDA 510(k) Premarket Notification

K250705 Sonata Transcervical Fibroid Ablation System 2.2

CLEARED

Apr 2, 2025
23 days to decision

K250705 · Product code: **KNF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k250705/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Mar 10, 2025
Decision date	Apr 2, 2025
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Gynesonics, Inc.**
Location	Redwood City, CA, US
Contact	Christine Ehmann
510(k) history	8 submissions · 8 cleared · 2006-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k250705/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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