

K240503 Sonata Transcervical Fibroid Ablation System 2.2Jul 17, 2024
147 days to decisionK240503 · Product code: **KNF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k240503/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Feb 21, 2024
Decision date	Jul 17, 2024
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240503/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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