

K211535 Sonata Transcervical Fibroid Ablation System 2.2Jun 17, 2021
30 days to decisionK211535 · Product code: **KNF** · Obstetrics & GynecologySource: <https://www.510kdatabase.net/k211535/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	May 18, 2021
Decision date	Jun 17, 2021
Days to decision	30 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.netDevice record: <https://www.510kdatabase.net/k211535/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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