

K193516 Sonata® Sonography-Guided Transcervical Fibroid Ablation System 2.1May 4, 2020
137 days to decisionK193516 · Product code: **KNF** · Obstetrics & Gynecology
Source: <https://www.510kdatabase.net/k193516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Dec 19, 2019
Decision date	May 4, 2020
Days to decision	137 days
Third-party review	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

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