FDA 510(k) Premarket Notification

K211535 Sonata Transcervical Fibroid Ablation System 2.2

CLEARED

Jun 17, 2021
30 days to decision

K211535 · Product code: **KNF** · Obstetrics & Gynecology
Source: 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