FDA 510(k) Premarket Notification

CLEARED

K173703 Sonata Sonography-Guided Transcervical Fibroid Ablation System

Aug 15, 2018
254 days to decision

K173703 · Product code: **KNF** · Obstetrics & Gynecology
Source: https://www.510kdatabase.net/k173703/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Coagulator-cutter, Endoscopic, Unipolar (and Accessories) (KNF)
Date received	Dec 4, 2017
Decision date	Aug 15, 2018
Days to decision	254 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