FDA 510(k) Premarket Notification

CLEARED

K251226 Aqua Medical RF Vapor Ablation System

Aug 8, 2025
109 days to decision

K251226 · Product code: **KNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k251226/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Apr 21, 2025
Decision date	Aug 8, 2025
Days to decision	109 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aqua Medical, Inc.**
Location	Santa Ana, CA, US
Contact	Scott McGill
510(k) history	5 submissions · 5 cleared · 2019-2025

REGULATORY CONSULTANT

Consulting firm	**ProMedoss, Inc.**
Contact	Bosmat Friedman-Cox

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov