FDA 510(k) Premarket Notification

CLEARED

K241271 Aqua Medical RF Vapor Ablation System

Dec 12, 2024
220 days to decision

K241271 · Product code: **KNS** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k241271/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	May 6, 2024
Decision date	Dec 12, 2024
Days to decision	220 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