

**K213627 RF Vapor System**Dec 17, 2021  
30 days to decisionK213627 · Product code: **KNS** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k213627/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Unit, Electrosurgical, Endoscopic (with Or Without Accessories) (KNS)
Date received	Nov 17, 2021
Decision date	Dec 17, 2021
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>ProMedoss, Inc.</b>
Contact	Bosmat Friedman

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

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