

**K210138 iTind System**Jun 25, 2021  
157 days to decisionK210138 · Product code: **QKA** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k210138/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Temporarily-placed Urethral Opening System For Symptoms Of Benign Prostatic Hyperplasia (QKA)
Date received	Jan 19, 2021
Decision date	Jun 25, 2021
Days to decision	157 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Medi-Tate , Ltd.</b>
Location	Or-Akiva, IL
Contact	Lihi Liviatan
510(k) history	2 submissions · 1 cleared · 2020-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Hogan Lovells US LLP</b>
Contact	Janice M. Hogan

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

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