

**K192357 INNOVO**Jan 16, 2020  
140 days to decisionK192357 · Product code: **QAJ** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k192357/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cutaneous Electrode Stimulator For Urinary Incontinence (QAJ)
Date received	Aug 29, 2019
Decision date	Jan 16, 2020
Days to decision	140 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Atlantic Therapeutics, Ltd.</b>
Location	Galway, IE
Contact	Anne-Marie Keenan
510(k) history	1 submissions · 1 cleared · 2020-2020

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