

**K181864 Polaris RF Ablation System**Jan 2, 2019  
174 days to decisionK181864 · Product code: **GXD** · Neurology  
Source: <https://www.510kdatabase.net/k181864/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Generator, Lesion, Radiofrequency (GXD)
Date received	Jul 12, 2018
Decision date	Jan 2, 2019
Days to decision	174 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Baylis Medical Company, Inc.</b>
Location	Mississauga, Ontario, CA
Contact	May Tsai
510(k) history	24 submissions · 24 cleared · 2012-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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