

**K201435 Molecular Flow Simulations**Dec 3, 2021  
550 days to decisionK201435 · Product code: **HAW** · Neurology  
Source: <https://www.510kdatabase.net/k201435/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Neurological Stereotaxic Instrument (HAW)
Date received	Jun 1, 2020
Decision date	Dec 3, 2021
Days to decision	550 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Therataxis, LLC</b>
Location	Baltimore, MD, US
Contact	Raghu Raghavan
510(k) history	1 submissions · 1 cleared · 2021-2021

**REGULATORY CONSULTANT**

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Consulting firm	<b>Convergent Clinical, Inc.</b>
Contact	Al Memmolo

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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