

**K242154 Numen™ Coil Embolization System**Sep 30, 2024  
69 days to decisionK242154 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k242154/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Jul 23, 2024
Decision date	Sep 30, 2024
Days to decision	69 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NumenFR™ Detachment System

**APPLICANT**

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Company	<b>MicroPort NeuroTech (Shanghai) Co., Ltd.</b>
Location	Shanghai, CN
Contact	Yuying Chen
510(k) history	3 submissions · 3 cleared · 2021-2024

**REGULATORY CONSULTANT**

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Consulting firm	<b>Biodesign Regulatory Services, LLC</b>
Contact	Ivory Chang

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242154/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026