

K203625 Numen Coil Embolization SystemSep 1, 2021
264 days to decisionK203625 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k203625/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Dec 11, 2020
Decision date	Sep 1, 2021
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	NumenFR Detachment System

APPLICANT

Company	MicroPort NeuroTech (Shanghai) Co., Ltd.
Location	Shanghai, CN
Contact	Qihua Zou
510(k) history	3 submissions · 3 cleared · 2021-2024

REGULATORY CONSULTANT

Consulting firm	Biodesign Regulatory Services, LLC
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)

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