FDA 510(k) Premarket Notification

K232955 Numen Coil Embolization System

CLEARED

Jan 10, 2024
111 days to decision

K232955 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k232955/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Sep 21, 2023
Decision date	Jan 10, 2024
Days to decision	111 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	Jiayin Sun
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

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Device record: https://www.510kdatabase.net/k232955/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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