FDA 510(k) Premarket Notification

K260351 Numen™ Helia Coil Embolization System

CLEARED

May 20, 2026
106 days to decision

K260351 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k260351/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Feb 3, 2026
Decision date	May 20, 2026
Days to decision	106 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	Yuying Chen
510(k) history	4 submissions · 4 cleared · 2021-2026

REGULATORY CONSULTANT

Consulting firm	**MicroPort CRM USA, Inc.**
Contact	John Skousen

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov