FDA 510(k) Premarket Notification

K262419 MICRUSFRAME (MFR100202)

CLEARED

Aug 14, 2026
30 days to decision

K262419 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k262419/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Jul 15, 2026
Decision date	Aug 14, 2026
Days to decision	30 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	MICRUSFRAME (MFR100253); MICRUSFRAME (MFR100305); MICRUSFRAME (MFR100356); MICRUSFRAME (MFR100407); MICRUSFRAME (MFR100412); MICRUSFRAME (MFR100509); MICRUSFRAME (MFR100517); MICRUSFRAME (MFR100611); MICRUSFRAME (MFR100626); MICRUSFRAME (MFR100713); MICRUSFRAME (MFR100730); MICRUSFRAME (MFR100816); MICRUSFRAME (MFR100829); MICRUSFRAME (MFR140225); MICRUSFRAME (MFR140303); MICRUSFRAME (MFR140304); MICRUSFRAME (MFR140306); MICRUSFRAME (MFR140406); MICRUSFRAME (MF

APPLICANT

Company	**Cerenovus, Inc.**
Location	Miami, FL, US
Contact	Ryan Rivera
510(k) history	10 submissions · 10 cleared · 2023-2026