

K212455 InZone Detachment SystemNov 16, 2021
103 days to decisionK212455 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k212455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Aug 5, 2021
Decision date	Nov 16, 2021
Days to decision	103 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Stryker Neurovascular
Location	Freemont, CA, US
Contact	Breskella Halteh
Website	https://www.stryker.com
510(k) history	32 submissions · 32 cleared · 2011-2026

Stryker Neurovascular is a medical device manufacturer based in Fremont, US. The company specializes in innovative interventional neurology solutions. Stryker Neurovascular has received FDA 510(k) clearances from total submissions since 2011. The company's portfolio is dominated by Neurology devices, representing 84% of regulatory submissions. The latest clearance was granted in 2026, demonstrating continued active development and market engagement. Recent cleared devices include intracranial base catheters, detachable coils, microcatheters, and thrombectomy retrievers. T...