

K210638 i-ED COIL SystemMar 26, 2021
23 days to decisionK210638 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k210638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Mar 3, 2021
Decision date	Mar 26, 2021
Days to decision	23 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Kaneka Medical America, LLC
Location	New York, NY, US
Contact	Audra Bogucki
510(k) history	2 submissions · 2 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	KANEKA Corporation
Contact	Takeaki Miyata

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k210638/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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