

**K192068 i-ED COIL**Apr 25, 2020  
268 days to decisionK192068 · Product code: **HCG** · Neurology  
Source: <https://www.510kdatabase.net/k192068/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Aug 1, 2019
Decision date	Apr 25, 2020
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Kaneka Pharma America, LLC</b>
Location	Hudson, NH, US
Contact	Kazuhiko Inoue
510(k) history	4 submissions · 4 cleared · 2010-2020

**REGULATORY CONSULTANT**

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Consulting firm	<b>KANEKA Corporation</b>
Contact	Takeaki Miyata

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k192068/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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