FDA 510(k) Premarket Notification

K192068 i-ED COIL

CLEARED

Apr 25, 2020
268 days to decision

K192068 · Product code: **HCG** · Neurology
Source: https://www.510kdatabase.net/k192068/

SUBMISSION DETAILS

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

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

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