

K203432 Axium Detachable CoilJul 7, 2021
226 days to decisionK203432 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k203432/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Nov 23, 2020
Decision date	Jul 7, 2021
Days to decision	226 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Axium Prime Detachable Coil

APPLICANT

Company	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Location	Lrvine, CA, US
Contact	Bhavika Patel
510(k) history	32 submissions · 32 cleared · 2014-2025

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