

K162704 Axium Prime Detachable Coil SystemJan 3, 2017
97 days to decisionK162704 · Product code: **HCG** · Neurology
Source: <https://www.510kdatabase.net/k162704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Device, Neurovascular Embolization (HCG)
Date received	Sep 28, 2016
Decision date	Jan 3, 2017
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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