

K222437 Aristotle Colossus GuidewireJan 26, 2023
167 days to decisionK222437 · Product code: **MOF** · Neurology
Source: <https://www.510kdatabase.net/k222437/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Guide, Wire, Catheter, Neurovasculature (MOF)
Date received	Aug 12, 2022
Decision date	Jan 26, 2023
Days to decision	167 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Scientia Vascular, Inc.
Location	West Valley City, UT, US
Contact	Max Alfonso
Website	https://www.scientiavascular.com/
510(k) history	7 submissions · 7 cleared · 2023-2026

Scientia Vascular, Inc. is a neurovascular medical device company focused on advanced access and therapy systems. The company operates with a manufacturing facility in West Valley City, US, and specializes in innovative guidewires, catheters, and microcatheters for minimally invasive neurological procedures. Scientia Vascular has received FDA 510(k) clearances from total submissions, with all submissions focused on Neurology devices. The company's regulatory activity spans from 2023 to 2026, with its most recent clearance in 2026, demonstrating continued innovation and ac...
