

**K243184 SAT CenterFlow Molding Balloon Catheter  
(IN20-00313)**Jun 25, 2025  
268 days to decisionK243184 · Product code: **DQY** · Cardiovascular  
Source: <https://www.510kdatabase.net/k243184/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Percutaneous (DQY)
Date received	Sep 30, 2024
Decision date	Jun 25, 2025
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>Strait Access Technologies Holdings</b>
Location	Cape Town, ZA
Contact	Malcolm Applewhite
510(k) history	1 submissions · 1 cleared · 2025-2025

**REGULATORY CONSULTANT**

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Consulting firm	<b>Medical Device Academy</b>
Contact	Robert Packard

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: [FDA accessdata.fda.gov](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k243184/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 13, 2026