FDA 510(k) Premarket Notification

CLEARED

K253652 Genie MAX Large Bore Introducer Sheath

Jan 22, 2026
63 days to decision

K253652 · Product code: **DYB** · Cardiovascular
Source: https://www.510kdatabase.net/k253652/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Introducer, Catheter (DYB)
Date received	Nov 20, 2025
Decision date	Jan 22, 2026
Days to decision	63 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cultiv8 1, LLC**
Location	Plymouth, MN, US
Contact	Robert Atkinson
510(k) history	1 submissions · 1 cleared · 2026-2026

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k253652/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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