

K250105 Boomerang Valvulotome (BMGVT080)Jul 3, 2025
169 days to decisionK250105 · Product code: **MGZ** · CardiovascularSource: <https://www.510kdatabase.net/k250105/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Valvulotome (MGZ)
Date received	Jan 15, 2025
Decision date	Jul 3, 2025
Days to decision	169 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Boomerang Push Valvulotome (BMGPVT125)

APPLICANT

Company	Aveera Medical, Inc.
Location	San Clemente, CA, US
Contact	Christopher Chapek
510(k) history	1 submissions · 1 cleared · 2025-2025

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