

**K251358 Bridge Plus Occlusion Balloon (590-002)**Jun 24, 2025  
55 days to decisionK251358 · Product code: **MJN** · Cardiovascular  
Source: <https://www.510kdatabase.net/k251358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular Occluding, Temporary (MJN)
Date received	Apr 30, 2025
Decision date	Jun 24, 2025
Days to decision	55 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Philips Image Guided Therapy Devices</b>
Location	Colorado Springs, CO, US
Contact	Sondra Chandler
510(k) history	1 submissions · 1 cleared · 2025-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251358/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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