

**K251955 Onflex™ Mesh**Jul 24, 2025  
29 days to decisionK251955 · Product code: **FTL** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k251955/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Mesh, Surgical, Polymeric (FTL)
Date received	Jun 25, 2025
Decision date	Jul 24, 2025
Days to decision	29 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Davol Inc., Subsidiary of C. R. Bard, Inc.</b>
Location	Warwick, RI, US
Contact	Mohammed Ahmed
510(k) history	3 submissions · 3 cleared · 2023-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k251955/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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