

K190268 Hydrofera Blue READY - BorderNov 6, 2019
271 days to decisionK190268 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k190268/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Feb 8, 2019
Decision date	Nov 6, 2019
Days to decision	271 days
Third-party review	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Hydrofera, LLC
Location	Willimantic, CT, US
Contact	Sean Anderson
510(k) history	7 submissions · 7 cleared · 1998-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190268/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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