

**K203480 DOUBLEFLO system**Apr 5, 2021  
129 days to decisionK203480 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k203480/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Nov 27, 2020
Decision date	Apr 5, 2021
Days to decision	129 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hemodia Sas</b>
Location	Labege, FR
Contact	Adeline Theron
510(k) history	4 submissions · 4 cleared · 2013-2023

**REGULATORY CONSULTANT**

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Consulting firm	<b>Visamed GmbH</b>
Contact	Arne Briest

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k203480/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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