

**K221919 DOUBLEFLO INFLOW/OUTFLOW PUMP, accessories  
and tubing sets**Mar 9, 2023  
251 days to decisionK221919 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k221919/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 1, 2022
Decision date	Mar 9, 2023
Days to decision	251 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

**REGULATORY CONSULTANT**

---

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](https://accessdata.fda.gov)510k Database - [www.510kdatabase.net](https://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k221919/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](https://accessdata.fda.gov). - Generated May 27, 2026