FDA 510(k) Premarket Notification

K250795 PUREVUE™ FMS

CLEARED

Dec 5, 2025
266 days to decision

K250795 · Product code: **HRX** · Orthopedic
Source: https://www.510kdatabase.net/k250795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Mar 14, 2025
Decision date	Dec 5, 2025
Days to decision	266 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**W.O.M. World of Medicine GmbH**
Location	Tucson, AR, US
Contact	Soeren Markworth
510(k) history	26 submissions · 26 cleared · 1992-2025