

K191579 Voyant SystemJul 11, 2019
27 days to decisionK191579 · Product code: **HRX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k191579/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Arthroscope (HRX)
Date received	Jun 14, 2019
Decision date	Jul 11, 2019
Days to decision	27 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Viseon, Inc.
Location	Irvine, CA, US
Contact	Cora Sim
510(k) history	2 submissions · 2 cleared · 2018-2019

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191579/> Data sourced from FDA 510(k) public records (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. - Generated June 28, 2026