

**K181885 Voyant System**Oct 2, 2018  
81 days to decisionK181885 · Product code: **HRX** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k181885/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Arthroscope (HRX)
Date received	Jul 13, 2018
Decision date	Oct 2, 2018
Days to decision	81 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k181885/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026