FDA 510(k) Premarket Notification

K191579 Voyant System

CLEARED

Jul 11, 2019
27 days to decision

K191579 · Product code: **HRX** · General & Plastic Surgery
Source: 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