July 11, 2019

Viseon, Inc.
Cora Sim
Regulatory Affairs Manager
13900 Alton Parkway, Suite 125
Irvine, California 92618

Re: K191579
Trade/Device Name: Voyant System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: June 13, 2019
Received: June 14, 2019

Dear Cora Sim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191579

Device Name
Voyant System

Indications for Use *(Describe)*
The Voyant System is indicated to provide minimally invasive access, visualization, illumination, and magnification of the surgical area of the spine.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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***Voyant System* 510(k) Summary – K191579**

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR §807.92, the following summary of information is provided:

A. Submitted by:

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Date Prepared: July 1, 2019

B. Device Name:

Trade or Proprietary Name:	*Voyant System*
Common or Usual Name:	Arthroscope
Classification Name:	Arthroscope
Device Class:	Class II
Classification:	21 CFR § 888.1100
Product Code:	HRX

C. Predicate Device:

The subject *Voyant System* is substantially equivalent to the predicate device, *Voyant System* (K181885).

D. Device Description:

The *Voyant System* is composed of the Voyant Sheath and Voyant Imager, and Accessories which includes an Image Control Box (ICB) and connecting cables. The Voyant Sheath and Voyant Imager are supplied sterile by ethylene oxide (EtO) while the ICB and connecting cables are supplied non-sterile and are reusable. The *Voyant System* is used in minimally invasive spine surgery to provide access and visualization of the surgical area of the spine.

The *Voyant System* is a sterile, single-use access and visualization device consisting of a Sheath for access to the spine and an Imager for illumination and visualization of the surgical area. The Sheaths are available in multiple diameters and lengths to accommodate a variety of patient anatomies and spinal surgical procedures. Likewise, the Voyant Imager is available in corresponding diameters to attach to the Voyant Sheath. The Voyant Imager connects to the Image Control Box (ICB) via an HDMI cable and live video image is displayed to a connected external HD monitor in the operating room. The ICB functions to power the Voyant Imager, process video data from the Voyant Imager to display live video image to the connected third-party HD Monitor.

The purpose of this submission is to implement design changes to the predicate *Voyant System* (K181885) to create a product line extension which includes the Voyant Sheath, Voyant Imager, and Accessories. These modifications to the *Voyant System* do not change the indications for use of the device, nor do they change the fundamental scientific technology of the device. Specifically, the following design and labeling modifications are described in this submission:

- Design modifications to the Voyant Sheath including additional diameters and lengths
- Material change of the patient contacting components of the *Voyant System*
- Design modifications to the Voyant Imager
- Design modifications to the Image Control Box (ICB)
- Labeling changes to include updated images and instructions based upon the modified subject device and additional warning based upon the improved performance of the subject device.

The models for the subject device are listed in the table below:

Voyant System Models:

	Model Number	**Package Contents****		
		Voyant Sheath		**Voyant Imager**
Sterile, Single-use, Voyant System	VSY-1640	16mm OD	40mm length	16mm OD
	VSY-1650		50mm length	
	VSY-1660		60mm length	
	VSY-1670		70mm length	
	VSY-1680		80mm length	
	VSY-1840	18mm OD	40mm length	18mm OD
	VSY-1850		50mm length	
	VSY-1860		60mm length	
	VSY-1870		70mm length	
	VSY-1880		80mm length	
	VSY-2040	20mm OD	40mm length	20mm OD
	VSY-2050		50mm length	
	VSY-2060		60mm length	
	VSY-2070		70mm length	
	VSY-2080		80mm length	
	VSY-2240	22mm OD	40mm length	22mm OD
	VSY-2250		50mm length	
	VSY-2260		60mm length	
	VSY-2270		70mm length	
	VSY-2280		80mm length	
	VSY-2640	26mm OD	40mm length	26mm OD
	VSY-2650		50mm length	
	VSY-2660		60mm length	
	VSY-2670		70mm length	
	VSY-2680		80mm length	
Non-sterile, Reusable, Accessories	ICB-02***	Voyant Image Control Box		

**One Voyant Sheath of specified diameter (OD) and length and one Voyant Imager of corresponding diameter (OD) are packaged together

***VLBL08-002 Operator's Manual

E. Indications for Use:

The *Voyant System* is indicated to provide minimally invasive access, visualization, illumination, and magnification of the surgical area of the spine.

F. Comparison of Technological Characteristics with the Predicate Device:

As was established in this submission, the subject *Voyant System* is substantially equivalent to the predicate *Voyant System* (K181885) previously cleared by FDA for commercial distribution in the United States. There have been no design changes to the devices previously cleared in the predicate 510(k). The subject device has been shown to be substantially equivalent and has equivalent technological characteristics to its predicate device through comparison in areas including design, labeling/intended use, principles of operation, materials, and function.

Design Comparison Table for Substantial Equivalence:

Feature	PREDICATE DEVICE	SUBJECT DEVICE
	Voyant System	***Voyant System***
510(k) Number	K181885	K191579
Product Code	HRX	Same
Indications for Use	The Voyant System is indicated to provide minimally invasive access, visualization, illumination, and magnification of the surgical area of the spine.	Same
Intended Use	Visualization of surgical area.	Same
Design	The Voyant System is an access and visualization system designed to provide illumination and magnification of the surgical area during minimally invasive spine surgery. The system consists of the Voyant Sheath and the Voyant Imager and Accessories. The Voyant Sheath is a tubular retractor used to provide access to the surgical area. The Voyant Imager is an external camera with LED light source that attaches to the Voyant Sheath. Accessories to the Voyant Imager include an Image Control Box (ICB) with connecting cables. The Image Control Box is a portable accessory used to control the image output of the Voyant Imager, which is displayed on a connected operating room HD monitor.	Same
Patient Contacting Materials (Tubular Retractor)	Anodized 6061-T6 Aluminum and medical grade plastic and adhesive	Parylene coated 6061-T6 Aluminum and medical grade adhesive

Feature	PREDICATE DEVICE	SUBJECT DEVICE
	Voyant System	***Voyant System***
Labeling (Single use/Reusable)	Voyant Sheath and Voyant Imager: Sterile, Single use Image Control Box and Connecting Cables: Non-sterile, Reusable	Same
Surgical Site Access Device	Tubular retractors	Same
Image Acquisition	Image acquisition is achieved through an integrated camera external to the surgical opening	Same
Image Processing	The image is digitally processed.	Same
Image Display	External monitor connection.	Same
Illumination	Illumination is achieved via direct transmission using an LED light source.	Same
Sterilization	Voyant Sheath and Voyant Imager: • Supplied sterile by Ethylene Oxide (EtO) to a sterility assurance level of 10^{-6}, for single use Image Control Box: Supplied non-sterile and reusable.	Same
Performance Characteristics	Camera resolution: 1080p Sensor resolution: 3280 x 2464 pixels Camera sensor: 1/4" CMOS Tubular retractor compressive force: ≥ 100N Image resolution: ≥ 11 lp/mm at 63mm Working length: 6-13cm	Camera resolution: Same Sensor resolution: Same Camera sensor: Same Tubular retractor compressive force: Same Image resolution: ≥ 11 lp/mm at 80mm Working length: 4-13cm

G. Performance Data

Non-clinical performance verification testing was performed to demonstrate that the subject *Voyant System* is substantially equivalent to the predicate device. Testing included design verification testing, software validation, electrical safety and electromagnetic emissions and immunity testing. Testing was performed in accordance with the following standards in order to establish equivalence to the predicate device:

Test/Document Description	Applicable Test Standard
Electrical Safety	IEC 60601-1
Electromagnetic Emissions and Immunity	IEC 60601-1-2
Software	IEC 62304
Risk Management	EN ISO 14971
Design Verification Testing	N/A

The results demonstrate that the subject *Voyant System* is substantially equivalent to the predicate.

H. Conclusions

Based on the indications for use, technological characteristics, non-clinical performance data, and a comparison to the predicate device, the subject *Voyant System* has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.