October 2, 2018

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

Re: K181885
Trade/Device Name: Voyant System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: July 12, 2018
Received: July 13, 2018

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K181885

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

***Voyant System* 510(k) Summary – K181885**

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: September 10, 2018

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, *Medtronic METRx System* (K002931).

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.

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. Substantial Equivalence:

Documentation that includes design verification testing results and detailed comparison to the predicate device demonstrates that the *Voyant System* is substantially equivalent to the following 510(k) cleared device:

Trade Name:	METRx™ System
Common Name:	Arthroscope
510(k) Clearance Number:	K002931

In addition, the *Voyant System* designates the following 510(k) cleared reference device:

Trade Name:	NeedleCam HD™ Visualization System
Common Name:	Arthroscope / Endoscope and Accessories
510(k) Clearance Number:	K143705

Substantial equivalence is based on intended use, technological characteristics, principles of operation, designs, and on bench testing performed.

The *Voyant System* subject of this 510(k) and the predicate METRx System have the same intended use. Specifically, the *Voyant System* and the predicate device are both arthroscopic devices intended to provide access and visualization of the surgical area.

Both the *Voyant System* and predicate device utilize aluminum alloy tubular retractors to provide access to the surgical area. The subject and predicate devices both utilize a camera component and light source to provide visualization and illumination of the intended surgical area, which is displayed on an external HD monitor. The surgical technique for creating a surgical incision and tissue dilation is the same for both the predicate and subject device. As shown in this submission, the differences in the indications for use, mainly, the *Voyant System* being indicated for the surgical area of the spine, versus the predicate METRx System being indicated for any area of the body, do not raise new questions of safety and effectiveness as both devices are intended to provide access and visualization of the intended surgical area.

As was established in this submission, the subject *Voyant System* is substantially equivalent to the predicate METRx System (K002931) previously cleared by the FDA for commercial distribution in the United States. The subject device has been shown to be substantially equivalent and have equivalent technological characteristics to its predicate device through comparison in areas including design, intended use, materials, and function.

G. Performance Data

Non-clinical 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, sterilization testing, and packaging and shelf-life validation 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
Sterilization	ANSI/AAMI/ISO 11135 ANSI/AAMI/ISO 11737-1 ANSI/AAMI/ISO 11737-2
Packaging and shelf-life	ISO 11607-1 ASTM F1980-16 ASTM F88/F88 M-15 BS EN 868-5 ASTM F 2096-11 ASTM D 4169-16 ISTA Procedure 2A
Electrical Safety	IEC 60601-1 IEC 60601-2-18
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

The subject *Voyant System* has been shown to be substantially equivalent to the legally marketed predicate device for its intended use.