February 19, 2021

Veran Medical Technologies, Inc.
B. Nathan Hunt
Vice President, Quality Assurance and Regulatory Affairs
1908 Innerbelt Business Center Dr
St. Louis, Missouri 63114

Re: K202346
Trade/Device Name: Veran SPiN Vision™ Bronchoscope System
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: January 15, 2021
Received: January 19, 2021

Dear B. Nathan Hunt:

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202346

Device Name
Veran SPiN VisionTM Bronchoscope System

Indications for Use *(Describe)*
The Veran SPiN VisionTM Single-Use Flexible Bronchoscope is intended to be used with the SPiN Vision™ Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Veran SPiN Vision™ Single-Use Flexible Bronchoscopes and SPiN Vision™ Video Processor are for use in hospitals, clinics, and/or urgent care centers by trained physicians.

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.

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K202346

510(k) Summary
Veran Medical Technologies, Inc.
SPiN Vision™ Bronchoscope System

In accordance with 21 CFR 807.92 the following summary of information is provided, on this date, January 14th, 2021:

1. 510(k) SUBMITTER

Veran Medical Technologies
1908 Innerbelt Business Center Drive
St. Louis, MO 63114
Tel: 314-659-8500
Fax: 314-659-8560

Contact Person:

B. Nathan Hunt
Vice President, Quality Assurance and Regulatory Affairs
Veran Medical technologies
1908 Innerbelt Business Center Drive
St. Louis, MO 63114
Tel: 314-659-8500
Fax: 314-659-8560

Date Prepared:

January 14th, 2021

2. DEVICE

Trade Name of Device:
Veran SPiN Vision™ Bronchoscope System
Models:

SYS-5100, SPiN Vision™ Video Processor
INS-7100, SPiN Vision™ Scope, 4.0mm OD, 2.0mm WC
INS-7130, SPiN Vision™ Scope, 6.0mm OD, 3.0mm WC

Common or Usual Name:
Bronchoscope (flexible or rigid) and accessories

Classification Names:
Bronchoscope (flexible or rigid) and accessories (21 CFR 874.4680)

Regulation Class: II

Classification Code: EOQ

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3. PREDICATE DEVICE

Predicate Device:

Trade Name: Vathin® Video Bronchoscope System

Common Name: Bronchoscope (flexible or rigid) and accessories

510(K) No.: K191828

Device Models:

Vathin®H-SteriScope™ I Single-use flexible Video Bronchoscope
BCV1-01 BCV1-02 BCV1-C1 BCV1-C2 BCV1-H1 BCV1-H2 BCV1-K1 BCV1-K2 BCV1-M1 BCV1-M2 BCV1-O1 BCV1-O2 BCV1-S1 BCV1-S2 BCV1-U1 BCV1-U2 BCV1-W1 BCV1-W2
Vathin®VisionCenterTM I Digital Video Processor DVP-A1

Classification Name: Bronchoscope (flexible or rigid) and accessories (21 CFR 874.4680)

Product Code: EOQ

Manufacturer: Hunan Vathin Medical Instrument Co., Ltd.

This predicate has not been subject to a design-related recall.

No reference devices were used in this submission.

4. DEVICE DESCRIPTION

The Veran SPiN Vision™ Bronchoscope System consists of the Veran SPiN Vision™ Single-Use Flexible Video Bronchoscope accessories (Model Nos. INS-7100 and INS-7130) and the Veran SPiN Vision™ Video Processor (Model: SYS-5100) for clinical image processing. The Veran SPiN Vision™ Single-Use Flexible Bronchoscope is introduced within the airways or tracheobronchial tree during Bronchoscopy. The Veran SPiN Vision™ Video Processor provides power and processes the images for medical electronic endoscope.

The Veran SPiN Vision™ Single-use Flexible Video Bronchoscope is a sterile, single use flexible bronchoscope. The Veran SPiN Vision™ Video Processor is a reusable device.

The light emitted by the LED cold light source of the Veran SPiN Vision™ Single-use Flexible Video Bronchoscope lens is irradiated into the body cavity, and the light reflected from the cavity enters the optical system and is imaged on the CMOS (complementary metal oxide semiconductor). The CMOS acquisition image is controlled by the CMOS drive circuit, and the standard color video signal is output to the Veran SPiN Vision™ Video Processor via the encoding circuit. The Veran SPiN Vision™ Video Processor adjusts the brightness of the light source or corrects the image according to the video signal output from the CMOS, and outputs the corrected standard color video signal.

The Veran SPiN Vision™ Single-use Flexible Video Bronchoscope has the following physical and performance characteristics:

- Maneuverable tip controlled by the user
- Flexible insertion cord
- Camera and LED light source at the distal tip
- Working channel
- Sterilized by Ethylene Oxide

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- For single use

The differences between the Veran SPiN Vision™ Single-use Flexible Video Bronchoscope models are as follow:

- Working channel diameters
- Insertion tube outer diameter

The Veran SPiN Vision™ Video Processor has the following physical and performance characteristics:

- Provides images from the Veran SPiN Vision™ Single-use Flexible Video Bronchoscope for observation
- Can connect to an external monitor
- Reusable device

5. INDICATION FOR USE

The Veran SPiN Vision™ Single-Use Flexible Bronchoscope is intended to be used with the SPiN Vision™ Digital Video Processor, endotherapy accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

The Veran SPiN Vision™ Single-Use Flexible Bronchoscopes and SPiN Vision™ Video Processor are for use in hospitals, clinics, and/or urgent care centers by trained physicians.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Veran SPiN Vision™ Bronchoscope System has the same technological characteristics and fundamental design as the predicate device. The Veran SPiN Vision™ Bronchoscope System and the predicate device are designed to provide real-time images to the physician in order to facilitate diagnostic and therapeutic procedures in the lung tract.

The differences between The Veran SPiN Vision™ Bronchoscope System and predicate device do not alter suitability of the proposed device for its intended use.

The Veran SPiN Vision™ Bronchoscope System is substantially equivalent to the cleared predicate device (K191828).

The Veran SPiN Vision™ Bronchoscope System has equivalent Indications for Use as the predicate device.

The subject and predicate device are similar in the following technological elements:

- They are single-use devices delivered sterile.
- They are flexible endoscopes with a maneuverable tip.

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- They are video endoscopes with a camera located in the distal tip to provide an image on a separate monitor.
- They use an LED-light source located in the distal tip.
- They have suction functionality.
- They have a working channel for insertion of endoscopic accessories.

The following technological differences exist between the subject and predicate device:

- The proposed device has different physical specifications.
- The conical lock/working channel port of the proposed device is compatible with existing biopsy valves.
- The steering level of the proposed device includes a locking function.
- The video processor of the proposed device has a different cable connector.

Non-clinical bench testing has been completed ensuring that the differences don't affect the safety and effectiveness of the proposed subject device.

7. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination:

- Declaration of Conformity with the product specific standards ISO 8600-1, ISO 8600-3, and ISO 8600-4
- Performance tests to test leaking, bending, articulating bending angle, endurance of the bending section, radius of the bending section and irrigation tests were performed.
- Packaging and labeling performance tests were performed
- Biocompatibility Test
- Aging Performance Test
- Sterile Packaging Integrity Test
- Electrical Compatibility according to IEC 60601-1-2
- Electrical Safety according to IEC 60601-1 and IEC 60601-2-18
- Color Performance Testing and Image Intensity Uniformity (IIU) Testing
- Software Verification and Validation Testing

Results: All tests passed.

8. CONCLUSION

The Veran SPiN Vision™ Video Bronchoscope System is substantially equivalent to its predicate device. The non-clinical testing demonstrates that the device is as safe and as effective and performs as well as the legally marketed device.