November 3, 2021

Verathon Medical (Canada) ULC
Teresa Davidson
Director, Regulatory Affairs
2227 Douglas Road
Burnaby, British Columbia V5C 5A9
Canada

Re: K211947
Trade/Device Name: GlideScope BFlex 2.8 Single-Use Bronchoscope
Regulation Number: 21 CFR 874.4680
Regulation Name: Bronchoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOQ
Dated: September 30, 2021
Received: October 4, 2021

Dear Teresa Davidson:

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,

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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)*

K211947

Device Name
GlideScope® BFlex™ 2.8 Single-Use Bronchoscope

Indications for Use *(Describe)*
GlideScope® BFlex™ Single-Use Bronchoscopes are intended to work with a video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment for endoscopy within the airways and tracheobronchial tree.

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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SECTION E: 510(K) SUMMARY

This summary of Safety and Effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR 807, Subpart E, section 807.92.

Submitter:

Verathon Medical (Canada) ULC
2227 Douglas Road
Burnaby, BC V3W 1P2
Canada

Contact Person:

Teresa Davidson
Director, Regulatory Affairs
Phone: (425) 629-5516
Email: Teresa.davidson@verathon.com

Date Summary Prepared:

October 21, 2021

Establishment Registration Number:

Verathon Medical (Canada) ULC
Registration Number: 9615393
Owner/Operator Number: 9095489

Device Trade or Proprietary Name:

GlideScope® BFlex™ 2.8 Single-Use Bronchoscope

Device Common or Usual Name:

Flexible Bronchoscope and accessories

Device Trade or Proprietary Name	Device Common or Usual Name
GlideScope® BFlex™ 2.8 Single-Use Bronchoscope	Flexible Bronchoscope and accessories

Device Classification:

Classification Name	Class	Product Code	Classification Regulation
Bronchoscope (Flexible or Rigid) and Accessories	II	EOQ	21 CFR 874.4680

Review Panel:

Ear, Nose, and Throat

Predicate Device:

The features and functions of the proposed GlideScope® BFlex™ 2.8 Single-Use Bronchoscope is substantially equivalent to the previously cleared GlideScope® BFlex™ 3.8, 5.0, and 5.8 Single-Use Bronchoscopes. The 510(k) clearance numbers and respective clearance dates for the predicate devices are included in the table below:

Predicate Device	510(k) Number	Clearance Date
GlideScope® BFlex™ 3.8 Single-Use Bronchoscope System	K193488	January 16, 2020
GlideScope® BFlex™ 5.0 Single-Use Bronchoscope System	K183256	January 04, 2019
GlideScope® BFlex™ 5.8 Single-Use Bronchoscope System	K191948	August 21, 2019

Device Description:

The GlideScope® BFlex™ 2.8 Single-Use Bronchoscope is one component of the GlideScope® BFlex™ Single-Use Bronchoscope System. The system consists of a single-use flexible bronchoscope, a reusable monitor, and a reusable cable. The GlideScope® BFlex™ Single-Use Bronchoscope System is intended to provide real time viewing and recording for a wide range of airway procedures.

Similar to the predicate GlideScope® BFlex™ 3.8, 5.0, and 5.8 Single-Use Bronchoscopes, the GlideScope® BFlex™ 2.8 Single-Use Bronchoscope is distributed sterile and is for single use only. The GlideScope® BFlex™ bronchoscopes operate with a portable reusable GlideScope video monitor (GVM or Core monitors) for purposes of image display.

Indications for Use:

GlideScope® BFlex™ Single-Use bronchoscopes are intended to work with a video monitor, in conjunction with non-powered endoscopic accessories and other ancillary equipment, for endoscopy within the airways and tracheobronchial tree.

Intended Patient Population:

The GlideScope® BFlex™ Single-Use system is for use in a hospital environment. The GlideScope BFlex bronchoscope is a single-use device designed for use in adults, with the BFlex 2.8 also designed for pediatric use (6 months to 6 years). It has been verified

and validated for the following endotracheal tube (ETT) and endoscope accessory (EA) sizes:

Model	Minimum ETT Internal Diameter	EA Minimum Working Channel Width
BFlex 2.8	4.0 mm	Not applicable
BFlex 3.8	5.0 mm	1.2 mm
BFlex 5.0	6.0 mm	2.1 mm
BFlex 5.8	7.0 mm	3.0 mm

Contraindications:

The GlideScope® BFlex™ 2.8 Single-Use Bronchoscope does not have a working channel and therefore cannot be used for therapeutic purposes.

Technological Characteristics:

The proposed subject GlideScope® BFlex™ 2.8 Single-Use Bronchoscope when compared to the predicate bronchoscopes has similar technological characteristics. See the comparison table below for similarities and differences between the proposed and predicate devices:

Technological Characteristic	Predicate GlideScope® BFlex™ 5.0 Single-Use Bronchoscope	Predicate GlideScope® BFlex™ 5.8 Single-Use Bronchoscope	Predicate GlideScope® BFlex™ 3.8 Single-Use Bronchoscope	Proposed GlideScope® BFlex™ 2.8 Single-Use Bronchoscope
Flexible Endoscope	Yes	Yes	Yes	Yes
Size Distinguishing Color (Non-patient contacting)	Blue	Yellow	Purple	Teal
Working Channel Material (Patient contacting)	Thermoplastic Polyurethane (Medical grade)	Thermoplastic Polyurethane (Medical grade)	Fluoropolymer (Medical grade)	Not applicable
Tip sheath adhesive and primer material (Patient contacting)	Cyanoacrylate adhesive and polyolefin primer	Same	Same	Same
Tip Sheath Material (Patient contacting)	Medical thermoplastic elastomers	Same	Same	Different Grade

Technological Characteristic	Predicate GlideScope® BFlex™ 5.0 Single-Use Bronchoscope	Predicate GlideScope® BFlex™ 5.8 Single-Use Bronchoscope	Predicate GlideScope® BFlex™ 3.8 Single-Use Bronchoscope	Proposed GlideScope® BFlex™ 2.8 Single-Use Bronchoscope
Braided Shaft Material (Patient contacting)	Medical thermoplastic elastomers	Same	Same	Different Grade
Outside Diameter of Flexible Insertion Tube/Shaft and Distal Tip	5.0mm	5.8mm	3.8mm	2.8mm
Minimum Internal Diameter of Working Channel	2.1mm	3.0mm	1.2mm	Not Applicable
Suction Port	Yes	Yes	Yes	Not Applicable
Accessory Port	Yes	Yes	Yes	Not Applicable
Single Use Bronchoscope	Yes	Yes	Yes	Yes
Sterility	Sterile by Ethylene Oxide (EO)	Same	Same	Same
Control Button for Tip maneuverability	Yes	Yes	Yes	Yes
Power Source	Rechargeable Lithium-ion Battery	Same	Same	Same
Camera	Yes	Yes	Yes	Yes
Direction of View, Relative to Center Line of Distal tip	0°	Same	Same	Same
Field of view, horizontal/vertical	85°	Same	Same	Same
Field of View, diagonal	120°	Same	Same	Same
Depth of Field	5-50mm	Same	Same	Same
Image Resolution	640x480	Same	Same	Same
LED Light Source	Yes	Yes	Yes	Yes
Image Display	Displays image on a Reusable Video Monitor	Same	Same	Same
Extended Viewing	Yes	Yes	Yes	Yes

Performance Testing:

Performance testing has been completed to demonstrate that the proposed GlideScope® BFlex™ 2.8 Single-Use Bronchoscope meets the safety and performance requirements established in the design specifications. Comprehensive verification and validation testing included the following:

- Full System Requirements Testing
- Electrical Safety according to
    - AAMI / ANSI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
    - IEC 60601-2-18: Edition 3.0 2009-08
      Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment
- Electromagnetic Compatibility according to
    - IEC 60601-1-2:2014 Ed.4.0/EN 60601-1-2:2015
      Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- Optical testing according to
    - ISO 8600-1:2015 (Ed. 4.0)
      Endoscopes - Medical endoscopes and endotherapy devices -- Part 1: General requirements
    - ISO 8600-3:2019 (Ed. 2.0)
      Optics and Optical instruments - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics
    - ISO 8600-4:2014 (Ed. 2.0)
      Endoscopes - Medical endoscopes and certain accessories - Part 4: Determination of maximum width of insertion portion
- Biocompatibility according to
    - ANSI AAMI ISO 10993-1:2018
      Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Aging Performance Testing
- Sterile Packaging Integrity Testing
- Cleaning Testing
- Design Validation
    - Usability study
      The usability study was conducted per:

- IEC 60601-1-6, General requirements for basic safety and essential performance – Collateral standard: Usability
- IEC 62366-1, 2015, Medical devices – Application of usability engineering to medical devices, which calls for usability and validation testing during medical device development, and
- AAMI HE75: 2009, Human factors engineering – Design of medical devices
- Guidance for Industry and Food and Drug Administration Staff, Applying Human Factors and Usability Engineering to Medical Devices (February 03, 2016)

The study was focused on user requirements and risk control measures related to the introduction of the smaller size GlideScope® BFlex™ 2.8 Single-Use Bronchoscope. Both pediatric (ages 6 months to 6 years old) and adult patient populations were considered. A comprehension test in addition to the simulated use scenarios was completed. All participants, overall, were able to operate the GlideScope® BFlex™ 2.8 Single-Use Bronchoscope safely and effectively. The result of this usability testing demonstrated that the GlideScope® BFlex™ 2.8 Single-Use Bronchoscope and associated labeling are safe and effective for the intended use, its intended users, and use environments.

Results: All testing resulted in acceptance criteria passed.

Summary of Clinical Tests:

The GlideScope® BFlex™ 2.8 Single-Use Bronchoscope, subject of this submission, did not require clinical studies to support the determination of substantial equivalence.

Conclusion:

The information in this 510(k) Premarket Notification demonstrates that the proposed GlideScope® BFlex™ 2.8 Single-Use Bronchoscope is substantially equivalent to the previously cleared predicate GlideScope® BFlex™ 3.8, 5.0, and 5.8 Single-Use Bronchoscopes with respect to safety, effectiveness, and performance.