May 3, 2023

Verathon Medical (Canada) ULC
Chauneen Wood
Director, RA
2227 Douglas Road
Burnaby, B.C. V5C 5A9
Canada

Re: K230948
Trade/Device Name: BFlex™ 2 Slim 3.8 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: April 1, 2023
Received: April 4, 2023

Dear Chauneen Wood:

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,

Shuchen Peng -S

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)*
K230948

Device Name
BFlex™ 2 Slim 3.8 Single-Use Bronchoscope

Indications for Use *(Describe)*
BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is intended to work with the 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.

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

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## 510(K) SUMMARY

This summary of Safety and Effectiveness is provided as part of this Premarket Notification in compliance with 21 CFR 80792.

**Submitter:**

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

**Contact Person:**

Chauneen Leah Wood M.S., RAC
Director, Regulatory Affairs
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Email: chauneen.wood@verathon.com

**Date Summary Prepared:**

March 31, 2023

**Establishment Registration Number:**

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

**Device Trade or Proprietary Name:**

BFlex™ 2 Slim 3.8 Single-Use Bronchoscope

**Device Common or Usual Name:**

Flexible Bronchoscope

| Device Trade or Proprietary Name | Device Common or Usual Name |
|---|---|
| BFlex™ 2 Slim 3.8 Single-Use Bronchoscope | Flexible Bronchoscope |

**Device Classification:**

| | |
|---|---|
| Device Panel<br>(Medical specialty) | Ear, Nose, and Throat Devices<br>Subpart E – Surgical Devices |
| Classification Regulation | 21 CFR 874.4680 |
| Classification Name | Bronchoscope (flexible or rigid) and accessories |
| Identification | A bronchoscope (flexible or rigid) and accessories is a tubular endoscopic device with any of a group of accessory devices which attach to the bronchoscope and is intended to examine or treat the larynx and tracheobronchial tree. It is typically used with a fiberoptic |

| | |
|---|---|
| Device Panel<br>(Medical specialty) | Ear, Nose, and Throat Devices<br>Subpart E – Surgical Devices |
| Classification Regulation | 21 CFR 874.4680 |
| | light source and carrier to provide illumination. The device is made of materials such as stainless steel or flexible plastic. This generic type of device includes the rigid ventilating bronchoscope, rigid nonventilating bronchoscope, nonrigid bronchoscope, laryngeal-bronchial telescope, flexible foreign body claw, bronchoscope tubing, flexible biopsy forceps, rigid biopsy curette, flexible biopsy brush, rigid biopsy forceps, flexible biopsy curette, and rigid bronchoscope aspirating tube, but excludes the fiberoptic light source and carrier. |
| Product Code | EOQ |
| Classification | Class II |

**Predicate Device:**

BFlex™ 2 Slim 3.8, and Ultraslim 2.8 Single-Use bronchoscopes are the legally market devices to which BFlex™ 2 Slim 3.8 Single-Use Bronchoscope claims substantial equivalence. The proposed BFlex™ 2 Slim 3.8 Single-Use Bronchoscope has the same intended use, and technological characteristics of the predicate. The predicates identified along with their 510(k) clearance numbers and respective clearance dates included in the table below:

| Predicate Device | 510(k) Number | Clearance Date |
|---|---|---|
| BFlex™ 2 Slim 3.8 Single-Use Bronchoscope System | K193488 | January 16, 2020 |
| BFlex™ 2 Ultraslim 2.8 Single-Use Bronchoscope System | K211947 | November 03, 2021 |

**Device Description:**

The BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is a component to the BFlex™ Single-Use Bronchoscope System. The BFlex™ Single-Use Bronchoscope system consists of a single-use flexible bronchoscope, a reusable monitor, and a reusable cable. The BFlex™ 2 Single-Use Bronchoscope System provides real time viewing and recording for a wide range of airway procedures.

**Indication for Use:**

The BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is 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 BFlex™ 2 Single-Use system is for use in a hospital environment. The BFlex™ 2 bronchoscope is a single-use device designed for use in adults, with the BFlex™ 2 Ultraslim 2.8 and BFlex™ Slim 3.8 also designed for pediatric use (Ultraslim 2.8—6 months to 6 years, Slim 3.8—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 Ultraslim 3.8 | 4.0 mm | - |
| BFlex™ 2 Slim 3.8 | 5.0 mm | 1.2 mm |

*Note: There is no guarantee that instruments selected solely using these instrument dimensions will be compatible in combination.*

**Technological Characteristics:**

The proposed BFlex™ 3.8 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:

Comparison Table

| Technological Characteristic | BFlex™ 2 Ultraslim 2.8 Single-Use Bronchoscope (Predicate) | BFlex™ 2 Slim 3.8 Single-Use Bronchoscope (Predicate) | BFlex™ 2 Slim 3.8 Single-Use Bronchoscope (Proposed) |
|---|---|---|---|
| Flexible Endoscope | Yes | Yes | Yes |
| Size Distinguishing Color (Non-patient contacting) | Teal | Purple | Purple |
| Outside Diameter of Flexible Insertion Tube/Shaft and Distal Tip | 2.8mm | 3.8mm | 3.8mm |
| Minimum Internal Diameter of Working Channel | Not Applicable | 1.2mm | 1.2mm |
| Suction Port | Not Applicable | Yes | Yes |
| Accessory Port | Not Applicable | Yes | Yes |
| Single Use Bronchoscope | Yes | Yes | Yes |
| Sterility | Sterile by Ethylene Oxide (EO) | Sterile by Ethylene Oxide (EO) | Identical |
| Control Button for Tip maneuverability | Yes | Yes | Yes |
| Power Source | Rechargeable Lithium-ion | Rechargeable Lithium-ion | Identical |
| Camera | Yes | Yes | Yes |
| Direction of View, Relative to Center Line of Distal tip | 0° | 0° | Identical |

| Technological Characteristic | BFlex™ 2 Ultraslim 2.8 Single-Use Bronchoscope (Predicate) | BFlex™ 2 Slim 3.8 Single-Use Bronchoscope (Predicate) | BFlex™ 2 Slim 3.8 Single-Use Bronchoscope (Proposed) |
|---|---|---|---|
| Field of view, horizontal/vertical | 85° | Identical | Identical |
| Field of View, diagonal | 120° | Identical | Identical |
| Depth of Field | 5-50mm | Identical | Identical |
| Image Resolution | 640x480 | 640x480 | Identical |
| LED Light Source | Yes | Yes | Yes |
| Image Display | Displays image on a Reusable Video Monitor | Displays image on a Reusable Video Monitor | Identical |
| Extended Viewing | Yes | Yes | Yes |

**Performance Testing:**

Performance testing has been completed to demonstrate that the proposed BFlex™ 2 Slim 3.8 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
    - ES60601-1:2005/(R)2012 and A1:2012 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
    - IEC 60601-2-18: Edition 3.0 2009-08 Particular requirements for the basic safety and essential performance of endoscopic equipment
- Electromagnetic Compatibility according to
    - IEC 60601-1-2:2014 Ed.4.0 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
  - ISO 10993-1:2018
    Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
- Sterile Packaging Integrity Testing
- Cleaning Testing
- Design Validation
  - Usability testing for the proposed BFlex 3.8 Single Use Bronchoscope for use with pediatric patients was conducted as part of the validation testing for the BFlex 2 family (all sizes). The usability study performed employed the same methods as was used for validation of the GlideScope BFlex 2.8 Single-Use Bronchoscope (K211947). The usability testing represents aa well-established method according to Section C of the "The Special 510(k) Program", Guidance for Industry ad Food and Drug Administration Staff (September 13, 2019).

    This study was conducted with two (2) user groups with thirty (30) representative end users. Primary users included one group of fifteen (15) pediatric anesthesiologists and one group of fifteen (15) adult intensivists or pulmonologists. The assessment was accomplished through thirteen (13) simulated use scenarios with pediatric Anesthesiologist and adult Intensivist/Pulmonologists.

    Overall performance using the BFlex 2 system was excellent with 99.97% task success rate for pediatric Anesthesiologists and adult Intensivists or Pulmonologists. The pertinent user and system requirements and results (Table L-5) associated with the pediatric claims for the proposed BFlex 2 Slim 3.8 Single-Use Bronchoscope device can be found in Section L, Table L-5 of the Special 510(k) application. Study data demonstrated based on observed participate performance and subjective assessments, that BFlex 2 bronchoscopes can be used by the intended users, in the intended use environment without patterns of crucial use error or unacceptable negative use-safety assessments.

Results: All testing resulted in acceptance criteria passed.

**Summary of Clinical Tests:**

The Clinical testing was not performed as non-clinical studies were sufficient to support substantial equivalence.

**Conclusion:**

The information in this 510(k) Premarket Notification demonstrates that the proposed BFlex™ 2 Slim 3.8 Single-Use Bronchoscope is substantially equivalent to the previously cleared predicate BFlex™ 2 Slim 3.8 and Ultraslim 2.8 Single-Use Bronchoscopes with respect to safety, effectiveness, and performance.