August 21, 2019

Verathon Medical (Canada) ULC
Haleh Ghassemi
Technical Manager, Regulatory Affairs
2227 Douglas Road
Burnaby, V5C 5A9 Ca

Re: K191948
Trade/Device Name: GlideScope BFlex 5.8 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: July 19, 2019
Received: July 22, 2019

Dear Haleh Ghassemi:

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/composition-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.


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
for Srinivas Nandkumar, 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
Device Name
GlideScope® BFlex™ 5.8 Single-Use Bronchoscope

Indications for Use
GlideScope® BFlex™ Single-Use Bronchoscopes are 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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- Department of Health and Human Services
- Food and Drug Administration
- Office of Chief Information Officer
- Paperwork Reduction Act (PRA) Staff
- PRASstaff@fda.hhs.gov

“As 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.”
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:

Haleh Ghassemi
Technical Manager, Regulatory Affairs
Phone: (425) 629-5517
Email: haleh.ghassemi@verathon.com

Date Summary Prepared:

July 19, 2019

Establishment Registration Number:

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

Device Trade or Proprietary Name:

GlideScope® BFlex™ 5.8 Single-Use Bronchoscope

Device Common or Usual Name:

Flexible Bronchoscope

<table>
<thead>
<tr>
<th>Device Trade or Proprietary Name</th>
<th>Device Common or Usual Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlideScope® BFlex™ 5.8 Single-Use Bronchoscope</td>
<td>Flexible Bronchoscope</td>
</tr>
</tbody>
</table>

Device Classification:

<table>
<thead>
<tr>
<th>Classification Name</th>
<th>Class</th>
<th>Product Code</th>
<th>Classification Regulation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bronchoscope (Flexible or Rigid) and Accessories</td>
<td>II</td>
<td>EOQ</td>
<td>21 CFR 874.4680</td>
</tr>
</tbody>
</table>
Review Panel:

Ear, Nose, and Throat

Predicate Device:

The features and functions of the proposed GlideScope® BFlex™ 5.8 Single-Use Bronchoscope is substantially equivalent to the previously cleared GlideScope® BFlex™ 5.0 Single-Use Bronchoscope. The 510(k) clearance number and respective clearance date for the predicate device is included in the table below:

<table>
<thead>
<tr>
<th>Predicate Device</th>
<th>510(k) Number</th>
<th>Clearance Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>GlideScope® BFlex™ 5.0 Single-Use Bronchoscope System</td>
<td>K183256</td>
<td>January 04, 2019</td>
</tr>
</tbody>
</table>

Device Description:

The GlideScope® BFlex™ 5.8 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™ 5.0 Single-Use Bronchoscope, the GlideScope® BFlex™ 5.8 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 monitor) for purposes of image display.

Intended 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. It has been verified and validated for the following endotracheal tube (ETT) and endoscope accessory (EA) sizes:

<table>
<thead>
<tr>
<th>Model</th>
<th>Minimum ETT Internal Diameter</th>
<th>EA Minimum Working Channel Width</th>
</tr>
</thead>
<tbody>
<tr>
<td>BFlex 5.0</td>
<td>6.0 mm</td>
<td>2.1 mm</td>
</tr>
<tr>
<td>BFlex 5.8</td>
<td>7.0 mm</td>
<td>3.0 mm</td>
</tr>
</tbody>
</table>
Technological Characteristics:
The proposed subject GlideScope® BFlex™ 5.8 Single-Use Bronchoscope when compared to the predicate bronchoscope has similar technological characteristics. See the comparison table below for similarities and differences between the proposed and predicate devices:

<table>
<thead>
<tr>
<th>Technological Characteristic</th>
<th>Predicate GlideScope® BFlex™ 5.0 Single-Use Bronchoscope</th>
<th>Proposed GlideScope® BFlex™ 5.8 Single-Use Bronchoscope</th>
</tr>
</thead>
<tbody>
<tr>
<td>Flexible Endoscope</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Outside Diameter of Flexible Insertion Tube/Shaft and Distal Tip</td>
<td>5.0mm</td>
<td>5.8mm</td>
</tr>
<tr>
<td>Minimum Internal Diameter of Working Channel</td>
<td>2.1mm</td>
<td>3.0mm</td>
</tr>
<tr>
<td>Suction Button</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Single Use Bronchoscope</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Sterility</td>
<td>Sterile by Ethylene Oxide (EO)</td>
<td>Same</td>
</tr>
<tr>
<td>Control Button for Tip maneuverability</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Power Source</td>
<td>Rechargeable Lithium-ion Battery</td>
<td>Same</td>
</tr>
<tr>
<td>Camera</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Direction of View, Relative to Center Line of Distal tip</td>
<td>0°</td>
<td>Same</td>
</tr>
<tr>
<td>Field of view, horizontal/vertical</td>
<td>85°</td>
<td>Same</td>
</tr>
<tr>
<td>Field of View, diagonal</td>
<td>120°</td>
<td>Same</td>
</tr>
<tr>
<td>Depth of Field</td>
<td>5-50mm</td>
<td>Same</td>
</tr>
<tr>
<td>Image Resolution</td>
<td>640x480</td>
<td>Same</td>
</tr>
<tr>
<td>LED Light Source</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Image Display</td>
<td>Displays image on a Reusable Video Monitor</td>
<td>Same</td>
</tr>
<tr>
<td>Extended Viewing</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Performance Testing:
Performance testing has been completed to demonstrate that the proposed GlideScope® BFlex™ 5.8 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
- Electromagnetic Compatibility according to
- Optical testing according to
- Biocompatibility according to
- Aging Performance Testing
- Sterile Packaging Integrity Testing
- Cleaning Testing
- Design Validation
Results: All testing resulted in acceptance criteria passed.

Summary of Clinical Tests:

The GlideScope® BFlex™ 5.8 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™ 5.8 Single-Use Bronchoscope is substantially equivalent to the previously cleared predicate GlideScope® BFlex™ 5.0 Single-Use Bronchoscope with respect to safety, effectiveness, and performance.