

K961832

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510(K) SUMMARY

1) Submitter:

Blue Ridge Products, LP
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Contact Person:

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Date of Summary Preparation:

August 12, 1996

2) Name of the Device:

Blue Ridge Products Laryngoscope Blade Cover

Common Name:

Blue Ridge Products Laryngoscope Blade Cover

Classification Name:

The product is an accessory to the Laryngoscope, Rigid, 73CCW

3) Legally Marketed Equivalent Device (Predicate Device):

The predicate device is the Slater Sleeve, which is a substantially equivalent device with a cleared 510(k) (K # 926158). It is currently marketed by Tadco, Inc.

4) A Description of the Device:

This device is a molded plastic cover for a laryngoscope blade. It is made in two models, for either the Miller #2 or the MacIntosh #3 laryngoscope blade. Also, a portion of the device covers the upper portion of the laryngoscope handle. The device functions to cover the laryngoscope blade prior to use in the mouth. The device is made of a linear low density polyethylene copolymer, approved by the FDA, 21 CFR 177.1520, and is 1 mm thick. The master file number is #11624. It is made to conform to the laryngoscope blade. The cover adheres to the laryngoscope blade by a plastic clip that is formed from the plastic material that encircles the top of the laryngoscope handle. It is a single use device.

5) Statement of Intended Use:

The intended use of this device is to cover the laryngoscope blade and the top of the handle during endotracheal intubation to possibly reduce the cleaning time of the laryngoscope blade.

This is the same intended use as the device identified as the predicate device above. The manufacturer's guidelines for cleaning the laryngoscope blade need to be followed.

6) A Summary of the Technological Characteristics of the Device Compared to the Predicate Device:

The function of the Blue Ridge device compared to the predicate device is the same, namely, they both cover the laryngoscope blade and the top portion of the handle. The predicate device is a loose fitting, flexible plastic, whereas the Blue Ridge device is molded to the shape of the laryngoscope blade. The predicate device is held in place by a rubber band around the end of the handle, whereas the Blue Ridge device is attached to the laryngoscope blade by a plastic clip around the top of the laryngoscope handle.

The non-clinical testing data comparing the Blue Ridge device and the Slater Sleeve are as follows:

	<u>The Blue Ridge Device</u>	<u>The Slate Sleeve Device</u>
Tensile Strength	1900 psi	1500-3500 psi (direction dependent)
Light Absorption	12 ± 2%	8 ± 2%
Ultimate Elongation	560%	2000-4000% (direction dependent)