May 15, 2026

Karl Storz Endoscopy-America Inc.
Jennifer Downing
Senior Regulatory Affairs Specialist
2151 E. Grand Avenue
El Segundo, California 90245

Re: K252624
Trade/Device Name: KARL STORZ Laryngoscopes and Accessories
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EQN
Dated: April 15, 2026
Received: April 15, 2026

Dear Jennifer Downing:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

JOYCE C. LIN -S

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)*
K252624

Device Name
KARL STORZ Laryngoscopes and Accessories

Indications for Use *(Describe)*

Laryngoscopes:
Model Numbers 8576A, 8576B, 8576C, 8576CC, 8576D, 8576E, 8587KK, 8588B, 8588BV, 8590K, 8590L
KARL STORZ distending and non-distending laryngoscopes and accessories are intended to create a working channel for minimally invasive investigations and treatments of the larynx for adult and pediatric patients. Models with a suction device connection are also used for suction.

Model Numbers 8574B, 8574C, 8574D, 8574E, 8574G, 8574JP, 8574SL, 8574SLS, 8574SSL, 8576AA, 8580B, 8582B, 8583B, 8587A, 8587AA, 8588A, 8589B, 8589C, 8590A, 8590AL, 8590B, 8590BL, 8590C, 8590CL, 8590DL, 8590DN, 8590J, 8590JA, 8590JL, 8590JV, 8590TV, 8661AN, 8661CN, 8661DN, 8661EN, 8666AN, 8666DN, 8668A, 8790A, 8790B, 8890A
KARL STORZ distending and non-distending laryngoscopes and accessories are intended to create a working channel for minimally invasive investigations and treatments of the larynx for adult patients. Models with a suction device connection are also used for suction.

Suction/Irrigation Tubes:
Model Numbers 8602KK, 8602KS, 8603KS, 8604KK
KARL STORZ suction/irrigation tubes are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ suction/irrigation tubes are used in minimally invasive investigations and treatments of the larynx for adult and pediatric patients.

Model Numbers 8602, 8603, 8604, 8602A, 8602K, 8602KA, 8602KV, 8603A, 8603K, 8603KA, 8603KV, 8604A, 8604E, 8691A, 8691B, 8691C, 8692A, 8692B, 8692C
KARL STORZ suction/irrigation tubes are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ suction/irrigation tubes are used in minimally invasive investigations and treatments of the larynx for adult patients.

Supporting Devices:
KARL STORZ supporting devices are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ supporting devices are intended for holding and supporting laryngoscopes for adult and pediatric patients.

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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510(k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92. All data included in this document is accurate and complete to the best of KARL STORZ's knowledge.

Submitter:	KARL STORZ SE & CO. KG (KST) Dr.-Karl-Storz-Straße 34 Tuttlingen, Baden-Wurttemberg, Germany, 78532 Establishment Registration Number: 9610617
Contact:	Jennifer Downing Senior Regulatory Affairs Specialist jennifer.downing@karlstorz.com Tel.: 1-424-218-8115
Date of Preparation:	May 13, 2026
Type of 510(k) Submission:	Traditional
Device Identification:	Trade Name: KARL STORZ Laryngoscopes and Accessories
Common Name:	Laryngoscopes and Accessories
Regulatory Class:	II
Product Code:	EQN
Classification Name:	874.4760 - Nasopharyngoscope (flexible or rigid) and accessories.
Device Panel:	Ear Nose & Throat
Predicate Device:	K953771 – KARL STORZ Laryngoscopes & Accessories The predicate device has not been subject to any recalls.
Reference Devices:	K944295 – KARL STORZ Laryngoscopes & Accessories K945237 – Suction/Irrigation Tubes and Cannulae ENT These reference devices have not been subject to any recalls.

Device Description:	**Laryngoscopes: Operating laryngoscopes** Operating laryngoscopes are used for examining and performing surgical interventions in the laryngeal region. The laryngoscopes consist of a rigid tube, which serves as a working channel, and a handle. Depending on the model, the proximal end enables connection to illuminating devices, smoke suction tubes, injection cannulas and telescopes. Laryngoscopes are used for examination of the larynx and depending on the model allow the visualization of the anterior commissure and subglottis. Instruments can be inserted through the working channel for surgical treatment of the larynx. For visualization a microscope or telescope can be used. **Laryngoscopes: Distending Operating Laryngoscopes:** The distending operating laryngoscopes ("distending laryngoscopes") have the same operating principle as the standard operating laryngoscopes with the addition of the possibility to adjust the upper and lower blade. There are two screws for this purpose; one to adjust the lumen and one to adjust the angle between upper and lower blade. **Supporting Devices** The supporting devices are used for the autonomous holding and supporting of operating laryngoscopes. They are designed for non-invasive use. A chest support consists of a laryngoscope holder and a support rod with a ring-shaped base. The laryngoscope holder is fixed into the handle of the laryngoscope and the support rod is inserted into the laryngoscope holder. The screw is tightened on the laryngoscope holder to make the entire assembly self-retaining. The chest support can be placed either directly on the chest of the patient or on a support table to enable autonomous holding of the operating laryngoscope. **Suction/Irrigation Tubes** In general, suction/irrigation tubes are used for manipulating and suctioning secretion or blood in the laryngeal region. The suction/irrigation tubes are used particularly with operating laryngoscopes in the larynx/pharynx region. All suction/irrigation tubes have a connection possibility to a tubing set proximally. The suction/irrigation lumen extends from the proximal to the distal end, at which one or more openings are arranged. Some suction tubes contain a cut-off hole on the handle for regulation of the suction power. Controlled by the

	handle and the selected suction or irrigation pressure of the pump, fluids can be introduced into or removed from the body through the suction tube.

Indications For Use:	**Laryngoscopes** Model Numbers 8576A, 8576B, 8576C, 8576CC, 8576D, 8576E, 8587KK, 8588B, 8588BV, 8590K, 8590L KARL STORZ distending and non-distending laryngoscopes and accessories are intended to create a working channel for minimally invasive investigations and treatments of the larynx for adult and pediatric patients. Models with a suction device connection are also used for suction. Model Numbers 8574B, 8574C, 8574D, 8574E, 8574G, 8574JP, 8574SL, 8574SLS, 8574SSL, 8576AA, 8580B, 8582B, 8583B, 8587A, 8587AA, 8588A, 8589B, 8589C, 8590A, 8590AL, 8590B, 8590BL, 8590C, 8590CL, 8590DL, 8590DN, 8590J, 8590JA, 8590JL, 8590JV, 8590TV, 8661AN, 8661CN, 8661DN, 8661EN, 8666AN, 8666DN, 8668A, 8790A, 8790B, 8890A KARL STORZ distending and non-distending laryngoscopes and accessories are intended to create a working channel for minimally invasive investigations and treatments of the larynx for adult patients. Models with a suction device connection are also used for suction. **Suction/Irrigation Tubes** Model Numbers 8602KK, 8602KS, 8603KS, 8604KK KARL STORZ suction/irrigation tubes are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ suction/irrigation tubes are used in minimally invasive investigations and treatments of the larynx for adult and pediatric patients. Model Numbers 8602, 8603, 8604, 8602A, 8602K, 8602KA, 8602KV, 8603A, 8603K, 8603KA, 8603KV, 8604A, 8604E, 8691A, 8691B, 8691C, 8692A, 8692B, 8692C KARL STORZ suction/irrigation tubes are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ suction/irrigation tubes are used in minimally invasive investigations and treatments of the larynx for adult patients. **Supporting Devices** KARL STORZ supporting devices are used with KARL STORZ distending and non-distending laryngoscopes. KARL STORZ supporting devices are intended for holding and supporting laryngoscopes for adult and pediatric patients.

Device Part Numbers , Technological Characteristics:

Operating Laryngoscopes

Article Number	Distal Diameter	Length (cm)
8661EN	11.5mm x 11.5mm	20
8574SSL	12.5mm	17.2
8574SL	12.5mm x 19.5mm	17
8574SLS	12.5mm x 19.5mm	17
8574JP	12.5mm x 20mm	15
8661DN	12mm x 10mm	19
8590TV	13.4m x 20.4mm	17
8580B	13.7mm x 17.2mm	17
8576E	13.9mm x 19mm	8.53
8576D	13.9mm x 19mm	9.53
8576C	13.9mm x 19mm	11.53
8574E	13mm	8
8574D	13mm	9.5
8574C	13mm	11
8590L	13mm	13
8590K	13mm	15
8661CN	14.5mm x 16.5mm	18
8590J	14.5mm x 20.5mm	18
8590JA	14.5mm x 20.5mm	18
8590JL	14.5mm x 20.5mm	22
8590DN	14mm	18
8589C	15.5mm x 18.5mm	17
8590JV	15mm x 21.8mm	19.7
8590C	16mm	17
8590CL	16mm	17
8590DL	16mm	18
8890A	16mm x 20mm	18
8576CC	17.3mm x 21mm	13
8590B	17.5mm	17
8590BL	17.5mm	17
8574G	17.8mm x 15.7mm	13.75
8589B	17mm x 22mm	17
8576AA	18.9mm x 28mm	18
8582B	18mm	12.5
8587KK	18mm x 20mm	11
8576B	19.4mm x 32mm	15.3
8583B	20mm	16
8587A	20mm x 24mm	15
8587AA	20mm x 24mm	17

8590A	21.5mm	17
8590AL	21.5mm	17
8576A	22.1mm x 32mm	16.5
8790B	25.5mm x 20mm	18
8790A	28mm x 22.5mm	17.5
8574B	8mm x 11.8mm	11

Distending Laryngoscopes

Article Number	Distal Width (Distending)	Distal Distension (distending only)	Length (cm)
8588A	22mm	15 - 65mm	22.6cm
8661AN	20mm	17.5 - 48.5mm	21.5
8666AN	24mm	19 - 42.9mm	21.5
8666DN	24mm	19 - 42.9mm	16.5
8668A	24.5mm	31.1 - 53.5mm	17.2
8588B	17mm	10 - 57mm	20.7cm
8588BV	17mm	10 - 57mm	20.7

Supporting Devices

Article Number	Description
8574KU	Laryngoscope Holder, w. adjustment wheel
8575GN	LEWY Laryngoscope Holder
8575KA	Laryngoscope Holder, GÖTTINGEN model
8575KB	Support Rod for 8575 K/KA
8575KD	Support Rod, 34 cm
8575L	Support Table, GÖTTINGEN model
8575LA (component of 8575L)	Clamp for support table 8575 L
8575LB (component of 8575L)	Holding rod for support table
8575LC (component of 8575L)	Swiveling arm for table 8575 L
8575V	Extension for 8575GB/GK/K
8580H	Laryngoscope Handle Extension, detachable

Suction/Irrigation Devices

Article Number	Outer diameter	Working length
8692A	1	20
8691A	1	20
8692B	1.5	20
8691B	1.5	20
8602KS	2	18
8602KK	2	18

8692C	2	20
8691C	2	20
8602K	2	23
8602KA	2	23
8602KV	2	23
8602A	2	23
8602	2	23
8603A	2.5	23
8603	2.5	23
8603KS	3	18
8604KK	3	18
8603K	3	23
8603KA	3	23
8603KV	3	23
8604A	3	23
8604	3	23
8604E	4	23

The comparison of technological characteristics with the predicate / reference devices are as follows:

Laryngoscopes:

	Subject Device KARL STORZ Laryngoscopes and Accessories: Laryngoscopes	**Predicate: K953771** KARL STORZ Laryngoscopes & Accessories: Laryngoscopes	**Reference Device: K944295** KARL STORZ Laryngoscopes & Accessories: Laryngoscopes
Types	Non-Distending and Distending Operating Laryngoscopes	Non-Distending Operating Laryngoscopes	Same as subject device
Length	8 – 22 cm	18 – 19 cm	8 – 25.5 cm

	Distal Diameter (non-distending)	7.7 – 19.4 mm (non-distending)	16 – 18 mm (non-distending)	10.5 – 18 mm (non-distending)
	Distal Width (Distending)	6 – 27 mm (distending)	Not applicable (no distending laryngoscopes)	12 – 24 mm (distending)
	Distal Distension (distending only)	At minimum distention: 11.6 – 26.5 mm At maximum distension: 38.7 – 65 mm	No distension	At minimum distention: 10 – 15 mm At maximum distension: 47 – 65 mm
	Finish	Smooth with a matte interior finish, or black all-over finish	Matte all-over finish or black all-over finish	Smooth exterior, interior not specified
	Localized textured finish on exterior to prevent tongue from slipping	Some models	Not available	Some models
	Adjustment of Lumen (Distending)	One wheel for setting the lumen integrated in the handle One screw for adjusting the lumen on the left side of the handle	Not applicable (no distending laryngoscopes)	One screw for adjusting the lumen on the left side of the handle One screw for adjusting the angle

		One screw for adjusting the angle		
	Channel / connection for telescope	No additional channel or 1 additional channel on the top of the working channel Fixation of the telescope by a telescope coupling with detachable latching function	No additional channel	No additional channel or 1 additional channel on the left side of the working channel Fixation of the telescope by a telescope coupling (cone/union nut)
	Interface light carrier, smoke suction tube and air injection cannula	Interface for connection of light carrier, smoke suction tube and injection cannula One on each side of the blade, or only one on one side of the blade and one on the top of the blade	Interface for connection of light carrier, smoke suction tube and injection cannula One on each side of the blade	Interface for connection of light carrier, smoke suction tube and injection cannula One on each side of the blade and one on the top of the blade
	Interface to prismatic light deflector	Interface to prismatic light deflector is available in the	No interface to prismatic light deflector available	Same as subject device

	handle of some laryngoscopes		
Sliding blade	Some laryngoscopes with sliding blade	No laryngoscopes with sliding blade	Same as subject device
Extended handle	Some laryngoscopes with extended handle	No laryngoscopes with extended handle	Same as subject device
Slotted blade	The blade of some laryngoscopes is open on the right side of the blade	No slotted laryngoscopes	Same as subject device
Interface to laryngoscope holder, handle and extension	Laryngoscopes with interface on the top of the handle for laryngoscope holder with shorter pin, handle and extension or for laryngoscope holder with longer pin	Laryngoscopes with interface on the top of the handle for laryngoscope holder with shorter pin, handle and extension	Same as subject device
Wings to prevent the tongue/soft tissue from	Some laryngoscopes with passively hinged wings	No wings	No wings

obstructing the lumen	on each side of the upper blade		
Integrated smoke suction channel	Some laryngoscopes with integrated smoke suction channel on the top of the handle	No integrated smoke suction tube but separate smoke suction tube can be attached	No integrated smoke suction tube but separate smoke suction tube can be attached
Integrated ventilation channel	Some laryngoscopes with integrated ventilation channel on the left side of the blade	No integrated ventilation channel but separate air injection cannula can be attached	No integrated ventilation channel but separate air injection cannula can be attached

Supporting Devices:

	Subject Device KARL STORZ Laryngoscopes and Accessories: Supporting Devices	**Reference Device: K944295** KARL STORZ Laryngoscopes & Accessories: Supporting Devices
Connection of laryngoscope holder to operating laryngoscope	Shorter pin or longer pin Screw for fixation	Same as subject device
Connection of laryngoscope	Clamp mechanism	Same as subject device

holder to handle		
Adjustment wheel on laryngoscope holder	Angle of laryngoscope holder can be adjusted	Same as subject device
Handle (8580H)	Detachable	Same as subject device
Support table	• Can be mounted on OR table equipped with standard sliding rail • Height adjustment Movable plate	Same as subject device
Length support rod	34 cm	21 - 37 cm
Type of support (rests on patient's chest or attached to a support table)	Stainless steel ring with silicone buttons and two set screws or no set screws Diameter 9 cm or 12 cm	Silicone "donut" ring without set screws or stainless steel bar with two set screws adjusting small steel feet that rest on the patient or support table. Diameter 9.5 cm
Extension (8575V)	Extension available to enlarge opening angle of the chest support rod for obese patients	No extension available

Suction Tubes:

	Subject Device: KARL STORZ Laryngoscopes and Accessories: Suction/Irrigation Tubes	**Reference Device: K945237** KARL STORZ Suction/Irrigation Tubes and Cannulae ENT
Working length	18 – 29.4 cm	6.5 – 50 cm
Outer diameter	1.1 – 4 mm	2.0 – 5.0 mm
Design of the distal end	Models with ball-shaped end or "normal" end. Distal end with one central opening or distal end closed with two lateral openings	Models with ball-shaped end or "normal" end. Distal end with one central opening
Design of the tube	curved upwards, straight	Same as subject device
Tubing connection for suction/ irrigation	LUER, olive	Olive
Design of the handle	Hand-shaped, finger grip plate, with cut-off hole	finger grip plate, with cut-off hole

Non-Clinical Performance Data:	There are no performance standards or special controls developed under Section 514 of the FD&C Act for Laryngoscopes and Accessories. However, the subject device follows the FDA recognized consensus standards and is tested according to the following standards and FDA Guidance: <u>Biocompatibility testing</u> The system complies with the following standards: • ISO 10993-1: Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process • ISO 10993-2: Biological evaluation of medical devices – Part 2: Animal welfare requirements • ISO 10993-5: Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity • ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests skin sensitization • ISO 10993-11: Biological evaluation of medical devices – Part 11: Tests for systemic toxicity • ISO 10993-12: Biological evaluation of medical devices – Part 12: Sample preparation and reference materials • ISO 10993-18: Biological evaluation of medical devices – Part 18: Chemical characterization of materials • ISO 10993-23 Biological evaluation of medical devices – Part 23: Tests for irritation • ISO 18562-1: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process • ISO 18562-2: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter • ISO 18562-3: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic substances • ISO 18562-4: Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate <u>Reprocessing Validation</u> The reprocessing data submitted complies with the following standards and guidance with regards to cleaning and sterilization:

- ISO 17664-1: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices
- TIR12:2020: Designing testing and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers
- ST79:2017: Comprehensive guide to steam sterilization and sterility assurance in health care facilities
- ISO 14937: Sterilization of health care products — General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices
- ISO 17665-1: Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices
- FDA Guidance Document Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling
- ANSI / AAMI ST98: Cleaning validation of health care products - Requirements for development and validation of a cleaning process for medical devices
- ANSI/AAMI ST77: Containment devices for reusable medical device sterilization

<u>Non-Clinical / Bench Performance Testing</u>

The following bench performance testing was performed:

- Laryngoscopes:
  - Photobiological safety per IEC 62471
  - Thermal safety per IEC 60601-2-18
  - Interlocking with accessories
  - Distending functionality (distending models only)
- Laryngoscopes and Supporting Devices:
  - Mechanical safety (bend resistance)
- Suction Tubes:
  - Suction and Irrigation flow rate
  - Leakage testing

Clinical Performance Data:	<u>Clinical Evidence:</u> A clinical literature review identified 46 scientific publications on the products in scope or closely related KARL STORZ products together with anatomical data and safety evidence from 20 additional studies on similar devices. The publications have been identified, assessed, and analyzed to provide support for the application in pediatric patients. Anatomical analyses confirm that the design, dimensions and intended supraglottic placement of the KARL STORZ Laryngoscopes are appropriate for use across pediatric age groups, with upper airway geometry and predominantly soft, flexible laryngeal structures supporting safe passage when used as intended. The clinical review evaluated the use of the laryngoscopes for a diverse group of conditions. The laryngoscopes serve as supporting devices that allow exposure of the airway for a planned procedure. The accessories were rarely mentioned, but they are routinely used with the laryngoscopes. Sample sizes varied between one and 191 subjects, with most studies reporting on 10 to 50 patients. Patients encompassed all age groups, including neonates, and studies were conducted globally. Procedural outcomes were mostly successful, and the adverse events reported were known procedural complications. Although the studies were not designed to assess device performance, the lack of any reported device-related complications supports the devices' overall safety. Additional review identified 20 publications describing use of similar devices with comparable anatomical access routes and mechanical interaction further supports the low incidence of adverse events and confirm that observed complications reflect known procedural risks of endotracheal intubation and laryngoscopic interventions.
Conclusion:	The conclusions drawn from the nonclinical tests and evidence from clinical literature demonstrate that the subject device, the KARL STORZ Laryngoscopes and Accessories, is substantially equivalent to the predicate device, which is currently marketed for the same intended use.