June 17, 2026

Stryker Instruments
Divya Sekar
Senior Principal, Regulatory Affairs Specialist
1941 Stryker Way
Portage, Michigan 49002

Re: K261544
Trade/Device Name: Hydro Irrigation System
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (flexible or rigid) and accessories
Regulatory Class: Class II
Product Code: EOB
Dated: May 8, 2026
Received: May 8, 2026

Dear Divya Sekar:

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,

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K261544

Please provide the device trade name(s).

Hydro Irrigation System

Please provide your Indications for Use below.

The Hydro Irrigation Console (console) and its accessories (also referred to as the Hydro Irrigation System) are intended for cleaning the distal lens of rigid endoscopes and maintaining clear visualization without removing the scope from the surgical site during otolaryngology procedures.

Please select the types of uses (select one or both, as applicable).

- [x] Prescription Use (21 CFR 801 Subpart D)
- [ ] Over-The-Counter Use (21 CFR 801 Subpart C)

Please select the age group(s) for which the device(s) is to be used.

- [ ] Neonates/Newborns (Birth to < 29 days old)
- [ ] Infants (29 days old to < 2 years old)
- [ ] Children (2 years old to < 12 years old)
- [ ] Adolescents (12 years old to < 22 years old)
- [ ] Adults (22 years old and greater)

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510(k) Summary – K261544

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R Part 807.92(c).

Submitter:

Applicant	Stryker Instruments 1941 Stryker Way Portage, MI 49002, USA
Contact Person	Divya Sekar Senior Principal, Regulatory Affairs Specialist Email: divya.sekar@stryker.com Phone: 408-764-6213
Date Prepared	May 8, 2026

Subject Device:

Name of Device:	Hydro Irrigation System
Common or Usual Name:	Irrigation Pump
Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories (21 CFR 874.4760)
Regulatory Class:	Class II
Product Code:	EOB
510(k) Review Panel:	Ear, Nose, & Throat

Predicate Device(s):

Karl Storz Clearvision Len Irrigation System	K013838 (predicate)
Hydro Irrigation System	K253679 (reference)
Smith & Nephew ENTire Irrigation Pump	K973286 (reference)

Device Description:

The Hydro Irrigation System is an irrigation device used for cleaning the distal lens of a rigid endoscope to maintain visualization during surgical procedures without removing the endoscope from the surgical site. The Hydro Irrigation System consists of three main components: (1) an irrigation console; (2) an irrigation cassette that inserts into the console, and (3) a foot switch that connects to the console. When actuated, the foot switch signals the console, which controls the operation and flow rate of irrigation fluid to the distal lens at the surgical site. The cassette draws irrigation fluid from the irrigation bag and delivers it to the distal lens through tubing and a connected sheath.

The Hydro Irrigation System provides two irrigation modes: Clean, which provides a brief stream over the distal lens of the endoscope to remove debris; and Flush, which delivers a

continuous stream to maintain a clear visualization at the surgical site. The Hydro Irrigation System also includes the optional RISE (Reimagined Integrated Surgical Experience) functionality, enabling integration with compatible Stryker devices via ethernet. RISE enhances workflow efficiency and reduces OR clutter by providing an extended user interface for controlling Hydro Console's power and irrigation settings.

Indications for Use:

The Hydro Irrigation Console (console) and its accessories (also referred to as the Hydro Irrigation System) are intended for cleaning the distal lens of rigid endoscopes and maintaining clear visualization without removing the scope from the surgical site during otolaryngology procedures.

Comparison of Technological Characteristics with the Predicate Device:

Feature	**Subject Device**	**Predicate Device**	**Reference Device**
	Hydro Irrigation System	**Clearvision Lens Irrigation System**	**Hydro Irrigation System**
Manufacturer	Stryker Instruments	Karl Storz	Same as subject device
Classification	Class II	Same as subject device	Same as subject device
FDA Product Code	EOB	Same as subject device	GWG
Classification Regulation	21 CFR 874.4760	Same as subject device	21 C.F.R. 882.1480
Classification Name	Nasopharyngoscope (flexible or rigid) and accessories	Same as subject device	Neurological Endoscope
Submission Number	K261544	K013838	K253679
Indications for Use	The Hydro Irrigation Console (console) and its accessories (also referred to as the Hydro Irrigation System) are intended for cleaning the distal lens of rigid endoscopes and maintaining clear visualization without removing the scope from the surgical site during otolaryngology procedures.	The KSEA Clearvision is a lens irrigation system for cleaning the distal lens of the telescope and maintaining clear visualization without removing the scope from the surgical site during sinus surgery.	The Hydro Irrigation Console (console) and its accessories (also referred to as the Hydro Irrigation System) are intended for cleaning the distal lens of rigid endoscopes and maintaining clear visualization without removing the scope from the surgical site during endoscopic neurosurgical procedures using an endonasal approach.
System Components	• Irrigation Console • Disposable Irrigation Cassette Tubing • Foot Switch	• Irrigation Console • Disposable Tubing set • Foot Switch	Same as subject device

Feature	Subject Device	Predicate Device	Reference Device
	Hydro Irrigation System	**Clearvision Lens Irrigation System**	**Hydro Irrigation System**
Principle of Operation	When actuated, the foot switch signals the console, which controls the operation and flow rate of irrigation fluid to the distal lens at the surgical site. The cassette draws irrigation fluid from the irrigation bag and delivers it to the distal lens through tubing and a connected sheath.	Same as subject device	Same as subject device
Irrigation Modes	• Clean • Flush	• Lens Cleaning • Irrigation	Same as subject device
Irrigation Settings User Interface	• Display Screen • Two (2) rotary knobs	A rotary knob	Same as subject device
Irrigation Console Design	• Microprocessor-controlled peristaltic pump • Irrigation and reverse flow with adjustable flow intervals	Same as subject device	Same as subject device
Compatible Devices	• Cleaning sheath • Rigid endoscopes • Device Control Console (optional RISE compatibility - K241401)	• Cleaning sheath • Rigid endoscopes	Same as subject device
Wireless Technology	• 4 Channel RFID	Not available	Same as subject device
Safety Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-4-2	Same as subject device	Same as subject device

Although the predicate device is indicated for use during sinus surgery, the lens-cleaning functionality during otolaryngology procedures is a recognized and well-established clinical practice, consistent with the legally marketed reference device: Smith & Nephew ENTire Irrigation Pump cleared under K973286.

Non-Clinical and/or Clinical Test Summary & Conclusion:

The Hydro Irrigation System was originally cleared under K253679. The indications for use statement for the Hydro Irrigation System have been modified to add otolaryngology procedures. This modification does not affect the safety or effectiveness of the device relative to the reference device (Hydro Irrigation System) as otolaryngology procedures are performed within the same endonasal endoscopic use environment as the cleared indications for use (i.e., endoscopic neurosurgical procedures using an endonasal approach). Additionally, the cleared

endonasal endoscopic neurosurgical procedures inherently rely on the nasal and sinus access corridors for neurosurgical intervention. There were no design changes needed or conducted to support the change in indications for use for the Hydro Irrigation System. As such, there was no requirement for additional performance testing. The verification and validation testing completed for the reference device is representative for the otolaryngology procedures. Therefore, we conclude that the Hydro Irrigation System is substantially equivalent to the legally marketed predicate device.