May 8, 2026

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

Re: K253679
Trade/Device Name: Hydro Irrigation System
Regulation Number: 21 CFR 882.1480
Regulation Name: Neurological Endoscope
Regulatory Class: Class II
Product Code: GWG
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,

JULIA E. SLOCOMB -S Digitally signed by JULIA E. SLOCOMB -S
Date: 2026.05.08 13:40:08 -04'00'

for Jaime Raben, Ph.D.
Director
DHT5A: Division of Neurosurgical, Neurointerventional, and Neurodiagnostic Devices
OHT5: Office of Neurological and Physical Medicine 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.	K253679

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 endoscopic neurosurgical procedures using an endonasal approach.

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

- ☒ Prescription Use (21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary – K253679

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: 408-754-2473
Date Prepared	May 2, 2026

Subject Device:

Name of Device:	Hydro Irrigation System
Common or Usual Name:	Irrigation Pump
Classification Name:	Neurological Endoscope (21 C.F.R. 882.1480)
Regulatory Class:	Class II
Product Code:	GWG
510(k) Review Panel:	Neurology

Predicate Device(s):

Karl Storz Clearvision II Len Irrigation System	K072410 (predicate)
Medtronic Integrated Power Console (IPC)	K081277 (reference[1])

NOTE 1: The reference device is intended to support scientific methods used for Performance - Bench testing of the Hydro Irrigation System.

NOTE 2: The predicate device has not been subject to a design-related recall.

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 endoscopic neurosurgical procedures using an endonasal approach.

Comparison of Technological Characteristics with the Predicate Device:

Feature	**Subject Device**	**Predicate Device**
	Hydro Irrigation System	**Clearvision II Lens Irrigation System**
Manufacturer	Stryker Instruments	Karl Storz
Classification	Class II	Same as subject device
Product Code	GWG	Same as subject device
Classification Regulation	21 C.F.R. 882.1480	Same as subject device
Classification Name	Neurological Endoscope	Same as subject device
Submission Reference	This submission	K072410
Intended Use	Lens cleaning during endoscopic procedures	Same as subject device
Indications for Use	NOTE 1	NOTE 2
System Components	• Irrigation Console • Disposable Irrigation Cassette Tubing* • Foot Switch **NOTE: Offers front-facing integrated irrigation tube set designed for improved usability.*	• Irrigation Console • Disposable Tubing set • Foot Switch
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

Feature	Subject Device	Predicate Device
	Hydro Irrigation System	**Clearvision II Lens Irrigation System**
Irrigation Modes	• Clean (Brief stream) • Flush (Continuous stream)	• Lens Cleaning (Brief stream) • Continuous Irrigation (Continuous stream)
Irrigation Settings User Interface	• Display Screen • Two (2) rotary knobs	A rotary knob
Irrigation Console Design	• Microprocessor-controlled peristaltic pump • Irrigation and reverse flow with adjustable flow intervals	Same as subject device
Compatible Devices	• Cleaning sheath • Rigid endoscopes • Device Control Console (optional RISE compatibility - K241401)	• Cleaning sheath • Rigid endoscopes
Wireless Technology	• 4 Channel RFID	• Not available
Safety Standards	• IEC 60601-1 • IEC 60601-1-2 • IEC 60601-1-6 • IEC 60601-4-2	Same as subject device

NOTE 1: 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.

NOTE 2: The KSEA Clearvision II 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 endoscopic neurosurgical procedures using an endonasal approach.

Performance Data:

The following performance data were provided in support of the substantial equivalence determination.

Test	Method	Result
Packaging and Shelf-Life	In accordance with FDA-recognized voluntary consensus standard ISO 11607-1:2019 (14-530)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 11607-2:2019 (14-531)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F2096-11:2019 (14-359)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F1886/F1886M-16 (14-501)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F88/F88M-23 (14-596)	Pass

Test	Method	Result
	In accordance with FDA-recognized voluntary consensus standard ASTM D4169-23 (14-576)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F1980-21 (14-575)	Pass
Biocompatibility	In accordance with FDA-recognized voluntary consensus standard ISO 10993-1:2018 (2-258)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-5:2009 (2-245)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-7:2008 (2-275)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-10:2021 (2-296)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-11:2017 (2-255)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-23:2021 (2-291)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F756-17 (2-250)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 10993-4: 2017/ AMD1:2025 (2-311)	Pass
	In accordance with FDA-recognized voluntary consensus standard ASTM F2901-19 (2-265)	Pass
Cleaning, Disinfection & Sterilization	In accordance with AAMI TIR12:2020 /(R)2023 (14-602)	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI AAMI ST98:2022 (14-583)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 17664-2:2021 (14-579)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 11135:2014 (14-529)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 11737-1:2018/AMD1:2021 (15-577)	Pass
	In accordance with FDA-recognized voluntary consensus standard ISO 11737-2:2019 (14-540)	Pass
	In accordance with FDA-recognized voluntary consensus standard ANSI/AAMI ST72:2019 (15-541)	Pass
Software	In accordance with FDA-recognized voluntary consensus standard IEC 62304:2006+A1:2015 (13-79)	Pass
Cybersecurity	In accordance with FDA Guidance for Industry and Staff - Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions (June 2025)	Pass
EMC, Wireless, Electrical, Mechanical, and Thermal Safety	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1:2020 (19-49)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC/TR 60601-4-2 (19-19)	Pass
	In accordance with FDA-recognized voluntary consensus standard AIM Standard 7351731 (19-45)	Pass

Test	Method	Result
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-2 (19-36)	Pass
	In accordance with FDA-recognized voluntary consensus standard IEC 60601-1-6 (5-132)	Pass
	FCC 47 CFR Part 15:2025, Radio Frequency Devices	Pass
Performance – Bench	In accordance with device input specifications, user needs and intended use	Pass
	Design Validation in Simulated Use Environment	Pass
	Human Factors and Usability Engineering	Pass

NOTE: Hydro Irrigation System does not require animal or clinical testing to support the determination of substantial equivalence.

Conclusions:

The Hydro Irrigation System is substantially equivalent in design, intended use, principles of operation, technological characteristics and safety features to the predicate device. Performance testing and risk analysis demonstrate that the Hydro Irrigation System is as safe and effective as the predicate device and does not raise new or different questions of safety and/ effectiveness introduced by the Hydro Irrigation System when used as instructed.