January 23, 2026

AB Medica SAS
℅ Joseph Azary
Regulatory Consultant
Aztech Regulatory & Quality LLC
543 Long Hill Avenue
Shelton, Connecticut 06484

Re: K252957
Trade/Device Name: Pneumo Dissector Hook
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope And Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 22, 2025
Received: December 22, 2025

Dear Joseph Azary:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Colin K. Chen -S
Digitally signed by Colin K. Chen -S
Date: 2026.01.23 12:59:05 -05'00'

Colin K. Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control 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.	K252957

Please provide the device trade name(s).

Pneumo Dissector Hook

Please provide your Indications for Use below.

The CO2 Pneumo-Dissector is used to dissect planes of soft tissue using pressure regulated, trigger-controlled pulses of medical grade CO2 gas. The device may be used in endoscopic, laparoscopic, and open procedures in which gentle blunt dissection of soft tissue planes is desired. Use the product only in accordance with the instructions provided.

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

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

510(k) Summary
Traditional 510(k)
Pneumo-Dissection Hook

1. SUBMITTER/510(K) HOLDER

AB Medica SAS
Les Petites Quarterees
Mery-Sur-Cher
Centre-Val de Loire
France 18100

Contact Name: Joseph Azary (Aztech Regulatory & Quality LLC)
Email: jazary@aztechregulatory.com or jazary@erols.com
Telephone: (203) 242-6670

Date Prepared: January 22, 2026

2. DEVICE NAME

Proprietary Name:	Pneumo Dissector Hook
Classification Name:	Laparoscope and Accessories
Common Name:	Pneumo Dissection Instrument
Classification Regulation:	21 CFR 876.1500
Product code:	GCJ
Classification:	Class 2

3. PREDICATE DEVICES

Predicate Type	Device Name	Manufacturer	510(k)	Product Code and Regulation
Primary	CO2 Pneumo Dissector	Cook Urological Inc	K972647	HET, 884.1720
Secondary #1	Nezhat-Dorsey Hydrodissection	American Surgical Instruments Inc	K913944	HET, 884.1720
Secondary #2	Hydro-Surg	Davol / Bard	K961492	GCJ, 876.1500

4. DEVICE DESCRIPTION

The Pneumo Dissector Hook is a standard monopolar hook (based on design cleared under K140101) that can deliver CO_2 flow on demand during general endoscopy and laparoscopic surgery. It is composed of two parts, a handle and an insert, which are linked using a nut-screw system. Also, the distal part of the instrument has the hook shape which is the monopolar electrode and the gas nozzle. It is a surgically invasive device intended for delivering pressurized CO_2 gas to achieve separation of tissue layers prior to their dissection. The hook insert and tube are offered in lengths of 330mm and 200mm and diameters of 3.5mm and 5.0mm.

Figure 1 Pneumo Dissector Handle and Insert

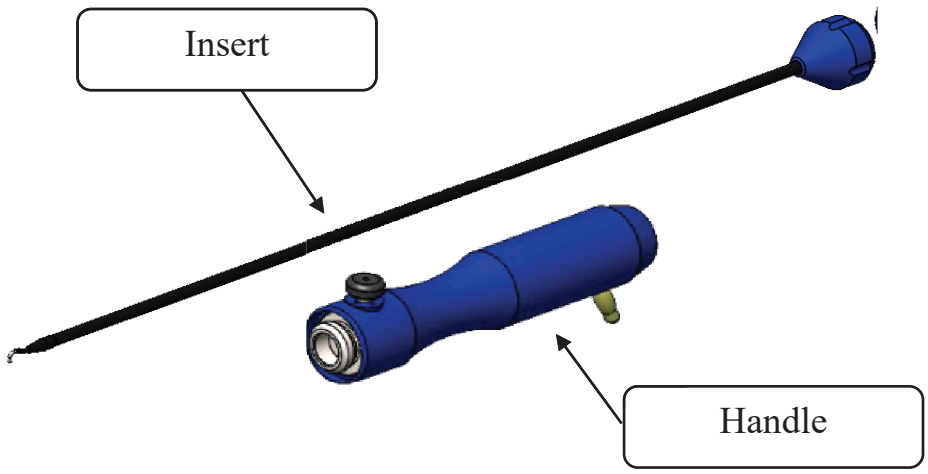
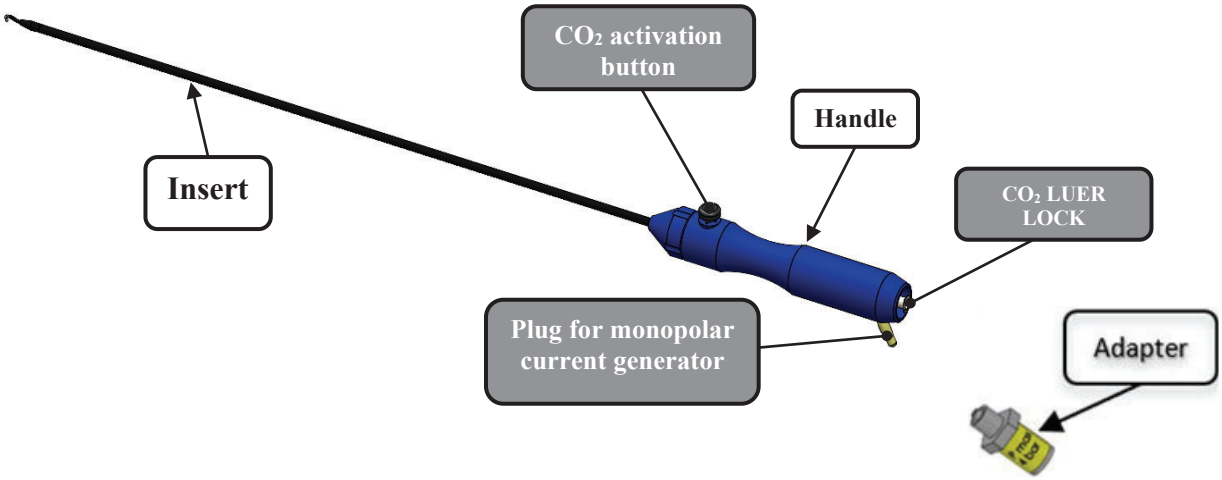


Figure 2 Pneumo Dissector Handle, Insert and adaptor (accessory)



The handle has a connector for the CO_2 as well as the banana plug or connector for electrosurgery. There is a push button to activate the CO_2.

The nut-screw system is used to link the handle to the insert.

The insert consists of an insulated tube with a hook on the distal end.

Specifications and Configurations

The hook insert and tube are available in lengths of 330mm and 200mm and diameters of 3.5mm and 5.0mm.

5. INTENDED USE / INDICATIONS FOR USE

The CO_2 Pneumo-Dissector is used to dissect planes of soft tissue using pressure regulated trigger-controlled pulses of medical grade CO_2 gas. The device may be used in endoscopic, laparoscopic and open procedures in which gentle blunt dissection of soft tissue planes is desired. Use the product only in accordance with the instructions provided.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

Substantial Equivalence Comparison Chart

Technological Characteristic	Subject Device Pneumo-Dissection Hook	Primary Predicate Cook K972647	Secondary predicate #1 American Surgical Instruments - HyNezhat-Dorsey HydroDissection System K913944	Secondary predicate #2 Bard Hydro-Surg irrigation system K961492	Comments
Indications for Use	The CO2 Pneumo Dissector is used to dissect planes of soft tissue using pressure regulated, trigger-controlled pulses of medical grade CO2 gas. The device may be used in endoscopic, laparoscopic and open procedures in which gentle, blunt dissection of soft tissue planes is desired. Use the product only in accordance with the instructions provided.	The CO2 Pneumo Dissector is used to gently dissect planes of soft tissue using short, pressure regulated, trigger-controlled pulses of CO2 gas. The device may be used in both open and laparoscopic procedures in which gentle, blunt dissection of soft tissue planes is desired.	Provide controlled powered irrigation to and aspiration of fluids from the operative site during laparoscopic procedures. It may also be used for resection of filmy adhesions (i.e. hydro dissection) and peritoneal lavage.	Controlled irrigation / aspiration during laparoscopic surgical procedures. It may also be used for resection of filmy adhesions (hydro-dissection) and peritoneal lavage.	Same All devices can be used for dissection. The Cook and AB Medica devices used CO2 (pneumo-dissection), whereas the Nezhat-Dorsey and Hydro-Surg use water (hydro-dissection).
Product Code Regulation	GCJ	HET	HET	GCJ	The subject device and secondary predicate #2 use the identical product code. Primary Predicate and Secondary

					predicate #1 uses a different code.
Dissection Method	Pressurized CO_2 Gas	Pressurized CO_2 Gas	Pressurized Fluid	Pressurized Fluid	All use external materials (water or gas) for dissection. The subject device and secondary predicate utilize CO2 whereas the primary predicate uses water.
Materials	Stainless Steel Shaft	Stainless Steel Shaft	Stainless Steel Shaft	Stainless Steel Shaft	SAME
Length	330mm (33cm) 200mm (20cm)	20cm – 35cm	28cm	28cm 33cm 46cm	SAME
Maximum Recommended Pressure	60 PSI	60 PSI	Not known	Not known	SAME The maximum pressure for subject device and predicate device is the same
Pressure Regulator	Use of external pressure regulator	Pressure regulator built into the handle which limited pressure to 60 psi	Is capable of high-pressure irrigation rates, but recommended uses minimum pressure necessary	Is capable of high-pressure irrigation rates, but recommended uses minimum pressure necessary	SAME The subject device and predicate device use regulator mechanisms
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide	SAME
Shaft Diameter	3.5-5.0mm diameter	3 – 10mm diameter	5-10mm diameter	5-10mm diameter	SIMILAR
Connecting Tube	Uses tubing to withstand maximum pressure	Uses tubing to withstand maximum pressure	Uses tubing to withstand maximum pressure	Uses tubing to withstand maximum pressure	SAME
Handle	Handle with push button to deliver CO_2	Handle with trigger to deliver CO_2	Trumpet valve with triggers to control flow	Trumpet valve with triggers to control flow	SAME
Electrosurgery Capability	Yes, the device has monopolar capability and can be used for electrosurgery. This was	No	Yes	Yes	The subject device has electrosurgery capability that has already been cleared under 510(k)

	originally cleared under K140101.				K140101.
Equivalence testing	The device was subject to performance testing compared to the Hydro-Sur / Nezhat Dorsey system and found to have equivalent performance	Not Available**	Yes. The device was subject to performance testing compared to the Hydro-Sur / Nezhat Dorsey system and found to have equivalent performance	Yes. The device was subject to performance testing compared to the Hydro-Sur / Nezhat Dorsey system and found to have equivalent performance	SAME

Operational and Technological Characteristics

The subject device is a pneumo-dissection hook indicated for diagnostic and therapeutic endoscopic, laparoscopic and open procedures. It consists of several components and accessories, including a handle, pneumo dissector hook, a CO_2 regulator and an adaptor. The pneumo-dissector is designed to be connected to a monopolar power generator using a cable, as well as to a CO2 source using a regulator and tubing. The device is connected to a regulator, which limits the pressure. The device has capability of electro-surgical cutting and cauterization and pneumodissection.

The primary predicate is a pneumodissection device whereas the secondary predicates are laparoscopic irrigation systems indicated to provide controlled powered irrigation of fluids to the operative site during laparoscopic procedures.

The secondary predicates consist of handpiece, electrical pump and probe tips. The handpiece uses a trumpet valve, which allows for variable flow control. The electrical pump has an ON/OFF switch for pump activation and is connected to the handpiece with conjoined tubing.

Summary of Similarities and Differences

The Subject Device has equivalent material composition, similar indications for use and system components as the predicates.

The subject device and primary predicate devices are both used for pneumodissection. The subject device and the secondary predicates utilize handheld designs, with controls built into the handheld piece. The subject device utilizes a handle, which has a button for control CO_2 emission and is designed to be held in a wrap grip. The secondary predicates have controls on the handpiece which can toggle the flow of water. The secondary predicates are designed to be held in either a pistol or trumpet grip and have multiple

buttons which allow for variable flow control and smoke evacuation. Though the subject device does not have controls for variable CO2 pressure on the handle, the pressure of the CO_2 is controlled by a pressure regulator, which is attached to the handle via an adaptor. The CO_2 regulator is pre-set with a maximum operating pressure of 60 PSI.

Both devices utilize single use inserts which are provided sterile via ethylene oxide. The subject device has a hook insert which is available in diameters of 3.5mm and 5.0mm and a length of 200mm and 330mm. The primary predicate offers probe tips with identical dimensions, though additional options are available.

7. PERFORMANCE TESTING

The device was subjected to the testing outlined below.

Peritoneum pressure with Pneumo-Dissector Hook action	The testing was a benchtop evaluation of pressure barrier, insufflator and standard. The pressure regulator of insufflator was set at 10mmhg. There will be 3 recording periods in 30 seconds. The use of the Pneumo Dissector hook must not impact the pressure of the pneumoperitoneum.	Check the gas flow by the use of the Pneumo Dissector hook will have no influence on peritoneum pressure regulation done by the laparoscopic insufflator.	PASS - The pneumodissector has no impact on the pressure of the pneumoperitoneum. The results meet the acceptance criteria.
Electro-thermal effect of the Pneumo-Dissector Hook	The testing will include a generator with 5mm range monopolar hook 5mm range pneumodissection hook handle and insert. The testing included testing on muscle, liver and kidney using different power settings, time and modes.	To determine the equivalence of the electro-thermal effect of the Pneumo Dissector hook compared to a classic 5mm range monopolar hook.	The test shows that the pneumodissection insert has equivalent electro-thermal effect to the C05 range insert.

Validation of automatic cleaning process	Visual inspection, measurement of TOC, and acceptable residues. After cleaning the devices must be absent of macroscopic soil, must have equal or less than 0.5 mg/device of TOC, and must have equal or less than 14 mg/device of cleaning agent residues.	To check the efficiency of the automatic cleaning process recommended by AB Medica SAS using worst case medical device.	The efficiency of the automatic cleaning process recommended by AB Medica SAS confirmed that visual, TOC and residual testing met requirements.
Validation of manual cleaning process	The test device will be inoculated with an organic soil of bovine serum, sheep blood and pork mucin. The device will be cleaned using Manual Cleaning Instructions. The acceptance criteria include meeting AMI TIR-30 guidelines for protein residuals and hemoglobin residuals.	To determine the efficacy of the specified cleaning procedure for test articles by a Total Protein and Hemoglobin Reduction Method.	The manual cleaning method met the AAMI TIR-30 guidelines for protein residuals and hemoglobin residuals.
Packaging Performance Testing for Sterile Medical Devices	Devices in packaging were subject to accelerated aging to simulate 3 years. The devices were conditioned at high temperatures and high humidity. Then subjected to drop testing, stacking, load vibration, altitude, random vibration and concentrated shock tests. The devices were subjected to visual inspection for seal integrity, dye penetration, peel test	To verify the integrity of packaging after accelerated aging, simulated transport conditions including visual inspection, peel testing and dye penetrant testing.	After undergoing accelerated aging according to ASTM F1980, 8 boxes were tested in transport according to ASTM D4169-16. After transport simulation, sealing validation tests were carried out on 3 x 81 samples according to the test methods defined in ISO 11607-1. The testing for CAR 23 111 passed visual inspection, integrity testing, peelability sealing, and resistance of sealing testing.

Ethylene Oxide Sterilization Requalification	The testing will be conducted in accordance with ISO 11135 to ensure that the sterilization process produces sterile medical devices.	The purpose of the study was to requalify the ethylene oxide sterilization process following change to packaging subcontractor, introduction of new devices and change of definition of maximum load.	The testing confirmed that the cycle including 180 minutes of conditioning and 240 minutes of gas exposure duration is requalified for routine sterilizations (providing sterile devices) of the devices from the configurations of minimal load to the maximal load in the autoclave at the contract sterilization.
Equivalence Test	The testing includes the subject device and the Bard HydroSurg with hook (Nezhat). The comparison was to include measuring output delivered at end of both hooks at varying loads (between 100 to 2000 ohms) and evaluate of thermal damage to muscle, liver and kidney tissue following pneumo or hydro dissection and cautery.	The purpose of the testing was to demonstrate equivalence between the subject device and available predicate (Bard Hydro-Surg with Nezhat Dorsey hook).	The testing confirmed that the output power delivered at end of the tips resulted in equivalent values between the subject device and secondary predicate. The testing also confirmed that the testing using muscle, liver and kidney tissue in cut modes (min, max and average) using Pneumo Dissector or hydro-dissection and cautery resulted in equivalent damage zones.

8. CONCLUSION

Any differences in the technological characteristics between the subject device, the predicate device, and secondary predicates do not raise different questions of safety or effectiveness. The data included in this submission demonstrates substantial equivalence to the predicate and secondary predicates listed above.
Overall, the subject devices have the following similarities to the primary predicate and secondary predicates: similar intended use, similar operating principles, incorporate identical materials, sterilized using similar materials and processes

The basis for the belief that the subject device is substantially equivalent to the predicate devices is summarized in the substantial equivalence table.