May 19, 2025

Selio Medical Limited
Colm McGarvey
CEO
Unit 53 Guinness Enterprise Centre,
Taylors Lane, Dublin 8
Dublin, D08 R9YW D08 R9YW
Ireland

Re: K243722
Trade/Device Name: Pre-B Seal Lung Biopsy Plug System - 15cm Model (FG0001); Pre-B Seal Lung Biopsy Plug System - 16cm Model (FG0002); Pre-B Seal Lung Biopsy Plug System - 20cm Model (FG0003)
Regulation Number: 21 CFR 878.4755
Regulation Name: Absorbable lung biopsy plug
Regulatory Class: Class II
Product Code: OMT

Dear Colm McGarvey:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated 4/8/2025. Specifically, FDA is updating this substantial equivalence (SE) letter as an administrative correction to include the intended IFU for K243722, as it was inadvertently excluded from our SE letter dated 4/8/2025.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Ethan Nyberg, Ph.D., OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT, and Dental Devices, 240-402-5973, Ethan.Nyberg@fda.hhs.gov.

Sincerely,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

April 8, 2025

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Regulation Number: 21 CFR 878.4755
Regulation Name: Absorbable Lung Biopsy Plug
Regulatory Class: Class II
Product Code: OMT
Dated: December 2, 2024
Received: December 3, 2024

Dear Colm McGarvey:

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,

Ethan L. Nyberg -S

Ethan Nyberg, Ph.D.
Assistant Director
DHT1C: Division of Anesthesia,
Respiratory, and Sleep Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243722

Device Name
Pre-B Seal Lung Biopsy Plug System - 15cm Model (FG0001);
Pre-B Seal Lung Biopsy Plug System - 16cm Model (FG0002);
Pre-B Seal Lung Biopsy Plug System - 20cm Model (FG0003)

Indications for Use *(Describe)*
The Pre-B. Seal Lung Biopsy Plug System is indicated for sealing pleural punctures to reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy needle entry site for visualization during surgical resection.
The Pre-B. Seal Lung Biopsy Plug System is indicated for use in adult patients (22 years of age and older).

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

Submitter

Name: Selio Medical Limited

Address: Unit 53 Guinness Enterprise Centre,
Taylors Lane,
Dublin 8,
Ireland,
D08 R9YW

Phone: 00 353 1 4100600
Contact Person: Colm McGarvey
Date Prepared March 7th, 2024

Device

Device Trade/Proprietary Name	Pre-B Seal Lung Biopsy Plug System
Device Common or Usual Name:	Absorbable lung biopsy plug
Regulatory Classification:	Class II
Classification Regulation:	21 CFR 878.4755 - Absorbable lung biopsy plug
Product Code:	OMT (Class 2) - Absorbable Lung Biopsy Plug
Classification Panel:	Anesthesiology

Predicate Device:

Primary Predicate Name and 510(k) Number: Bio-Seal Lung Biopsy Tract Plug System (DEN090007).

This predicate has not been subject to a design-related recall. There are no reference devices identified in this submission.

Device Description

The Pre-B. Seal Lung Biopsy System is a sterile single-use medical device comprised of the following components:

- Prefilled Hydrogel Syringe
- Delivery System 15cm length, 16cm length, 20cm length

The model numbers are:

- Pre-B. Seal Lung Biopsy Plug System 15cm (Model # FG0001)
- Pre-B. Seal Lung Biopsy Plug System 16cm (Model # FG0002)
- Pre-B. Seal Lung Biopsy Plug System 20cm (Model # FG0003**)**

The Delivery System is comprised of an introducer pre-assembled with a delivery needle, with depth markings on the external surface of the introducer. The delivery needle and introducer are both constructed of stainless steel. A pebax white depth marker ball sits on the introducer and may be used in addition to the markings as a depth indicator. The delivery system is ethylene oxide (EO) sterilized and is patient contacting (≤ 24 hours (includes transient contact).
The prefilled syringe contains a sealant (hydrogel) which acts as an absorbable lung biopsy plug. The hydrogel plug consists of gelatin, saline and hyaluronic acid. The plug is provided in ready to use configuration within a prefilled hydrogel syringe. The hydrogel is biodegradable.
The prefilled hydrogel is steam sterilized. The hydrogel is patient contact (> 30 days (i.e., permanent))
The syringe is indirect patient contacting.

These components have been designed for use during a CT-guided transthoracic lung biopsy procedure. The syringe is attached to the delivery system and then purged using a standard hypodermic purging technique outside of the patient. The distance from the skin to the pleura surface is measured using CT imaging, and using this information, the device is advanced to the intended deployment location within the lung under CT guidance. The hydrogel plug is deployed via the prefilled syringe below the surface of the lung through the delivery system. The hydrogel plug creates a seal around the delivery system through which a biopsy is conducted. When the biopsy is complete, the delivery system is withdrawn, and the hydrogel plug remains in place to fill the void and marks the biopsy needle entry site for visualization during surgical resection. The hydrogel plug is biodegradable and resorbs over approximately 49 days

Indications for use

The Pre-B. Seal Lung Biopsy Plug System is indicated for sealing pleural punctures to reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy needle entry site for visualization during surgical resection.

The Pre-B. Seal Lung Biopsy Plug System is indicated for use in adult patients (22 years of age and older).

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Pre-B. Seal Lung Biopsy Plug System is substantially equivalent (SE) to the Bio-Seal Lung Biopsy Tract Plug System (DEN090007) based on the similar functional and performance characteristics of the subject device when compared to the predicate device. The minor differences between the subject device and predicate device do not raise concerns of safety and effectiveness. A side-by-side comparison of the technological characteristics of the subject device and the predicate device, supports a determination of substantial equivalency (SE) per table 1 below.

Table 1: Comparison of technological characteristics with the predicate device.

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
Intended Use	Intended to provide accuracy in marking a biopsy needle entry site for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies.	Intended to provide accuracy in marking a biopsy location for visualization during surgical resection and closure of pleural punctures associated with percutaneous, transthoracic needle lung biopsies.	Same (substantially equivalent)
Indications for use	Indicated for sealing pleural punctures to reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy needle entry site for visualization during surgical resection. Indicated for use in adults (22 years of age and older)	Indicated for sealing pleural punctures to significantly reduce the risk of pneumothoraces (air leaks) associated with percutaneous, transthoracic needle lung biopsies and to provide accuracy in marking a biopsy location for visualization during surgical resection.	Same (substantially equivalent)
Device Class	Class II	Class II	Same (Substantially Equivalent)
Product Code	OMT, 21CFR878.4755	OMT, 21CFR878.4755	Same (Substantially Equivalent)
Prescription device	Yes	Yes	Same (Substantially Equivalent)
Single-Patient Use	Yes	Yes	Same

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
			(Substantially Equivalent)
Target population	Adult patients (22 years of age and older) requiring lung biopsies	Patients requiring lung biopsies	Same (Substantially Equivalent)
Anatomical site	Lung biopsy locations	Lung biopsy locations	Same (Substantially Equivalent)
Ability to determine depth	Depth placement of the proposed device is primarily determined using CT guidance. This is supplementary to depth markings and depth marker ball on the device delivery system to add depth determination.	Depth placement of the predicate device is primarily determined using CT guidance. This is supplementary to depth markings on the device delivery system (with the depth set via a thumb wheel) to add depth determination.	Same (Substantially Equivalent) Both the proposed and predicate device primarily determine depth using CT guidance. Both devices also provide for a measurement of depth using markings on the delivery system which aid deployment of the plug at the required depth. The differences between use of depth markings and a depth marker ball (proposed device) versus thumb wheel (predicate device), supplementary to CT guidance, to assist physicians in determining depth does not raise new or different questions of safety or effectiveness. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, and usability testing on the proposed device demonstrated the devices ability to determine depth, and therefore there are no

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
			new or different questions of safety and effectiveness.
Environment of use	Hospital	Hospital	Same (Substantially Equivalent)
Components Provided	1) Prefilled hydrogel syringe (which contains pre-formulated ready to use hydrogel.) 2) Delivery system comprised of an introducer with depth marker ball, pre-assembled with a delivery needle. The introducer contains depth markings. The delivery system is connected to the syringe and purged, before advancement into the lung for deployment of the plug at the desired depth.	1) Co-axial Adapter housing containing the pre-formed dehydrated hydrogel plug. The plug is hydrated with saline (not provided with the device) at time of use. 2) Delivery System comprised of a handle containing depth markings, a depth adjustable thumb wheel, a depth locking mechanism and the plunger stylet. The delivery system is connected to the coaxial adapter, which is then connected with the biopsy introducer (left in place after the biopsy procedure), before deployment of the plug to the desired depth.	Substantially Equivalent Both the proposed and predicate device include a hydrogel plug that is deployed via the delivery system. The differences between the configurations of the hydrogel and delivery system do not raise new or different questions of safety or effectiveness. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, and usability testing on the proposed device demonstrated the device's ability to deploy the hydrogel via the delivery system, and therefore there are no new or different questions of safety and effectiveness.
Hydrogel Plug provided ready for use.	The hydrogel plug is provided in a prefilled hydrogel syringe, it is pre-formulated and ready to use.	The hydrogel plug is pre-formed and dehydrated. It is contained within a coaxial adapter. The plug needs to be first hydrated using saline (not provided with the device) at time of use. Upon hydrating with saline, the plug should be deployed within thirty (30) seconds of securing the coaxial adapter to the introducer. Hydration	Different The proposed device hydrogel plug is provided pre-formulated, ready to use, and does not require any preparation at the time of use, unlike the predicate device which must be hydrated with saline (not provided with the device).

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
		and swelling of the predicate plug begins upon exposure to fluid, and per the manufacturer's instructions for use, delays may lead to difficulties or inability to deploy.	The proposed plug requires fewer preparation steps when compared to the predicate, and the time period for deployment is not constrained. The difference in hydrogel plug configuration between the proposed and predicate device does not raise new or different questions in relation to safety and effectiveness, and both plugs have the same intended use. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, usability testing and biocompatibility testing on the proposed device demonstrated the hydrogel's performance and therefore there are no new or different questions of safety and effectiveness.
Delivery System that deploys the plug	The delivery system comprises of an introducer with depth marker ball, pre-assembled with a delivery needle. The introducer contains depth markings and a depth marker ball. The delivery system is attached to the prefilled hydrogel syringe. The device is purged before being advanced into the lung under CT imaging for deployment of the hydrogel plug.	Delivery System comprised of a handle containing depth markings, a depth adjustable thumb wheel, a depth locking mechanism, and a plunger stylet. The predicate requires a Biopsy introducer (with depth markings), which is not supplied with the predicate device. The biopsy introducer remains in place after the biopsy procedure. The plug is inserted via the plunger stylet through the co-axial adapter (containing the plug) and biopsy introducer, to the required depth for	Substantially equivalent Both the proposed and predicate device contain delivery systems which are used for deployment of the hydrogel plug. The differences between how plug deployment is performed do not raise new or different questions of safety or effectiveness. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, and usability testing on the proposed device demonstrated the delivery system ability to deploy the plug and therefore there are no

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
		deployment under CT imaging.	new or different questions of safety and effectiveness.
Absorbable Lung Biopsy Plug	Hydrogel Plug is biodegradable, thus absorbable.	Hydrogel Plug is biodegradable, thus absorbable.	Same (Substantially Equivalent) Both the proposed and predicate device contain a hydrogel plug that is biodegradable, thus absorbable. GLP animal testing where the proposed device and predicate devices were compared, demonstrated the hydrogel plug is absorbable, therefore there are no new or different questions of safety and effectiveness.
Hydrogel plug seals pleural punctures associated with percutaneous, transthoracic needle lung biopsies	The proposed device plug is provided ready-to-use and is deployed beneath the surface of the visceral pleura forming a viscous plug before the biopsy procedure. This viscous plug is intended to reduce air leakage from the lung by sealing any tract/gap created during the puncturing of the visceral pleura membrane of the lung. The hydrogel remains in situ until the pleural puncture has healed and then resorbs over time.	The predicate device plug is desiccated and is prepared at the time of use. The plug is deployed into the needle tract post the biopsy procedure. The plug is intended to reduce air leakage from the lung by sealing the needle tract created. The hydrogel remains in situ until the pleural puncture has healed and then resorbs over time.	Same (Substantially Equivalent) Both the proposed and predicate device hydrogel plugs seal pleural punctures associated with percutaneous, transthoracic needle lung biopsies. The differences between plug configurations or procedure for deployment do not raise new or different questions of safety or effectiveness. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, and usability testing on the proposed device demonstrated the plugs ability to seal pleural punctures associated with percutaneous, transthoracic needle lung biopsies, and therefore there are no new or different questions of safety and effectiveness.

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
Hydrogel plug remains at the site of deployment	The hydrogel plug remains at the site of deployment	The hydrogel plug remains at the site of deployment	Same (Substantially Equivalent) Both the proposed and predicate device hydrogel plug remains at the site of deployment, The differences between plug configurations or procedure for deployment do not raise new or different questions of safety or effectiveness. Bench testing, GLP animal testing where the proposed device and predicate devices were compared, and Usability testing on the proposed device demonstrated hydrogel plug remains at the site of deployment.
Hydrogel plug resorbs over time	The hydrogel plug resorbs over approximately 49 days	The predicate device resorbs within 20 months as detailed within the predicate De Novo: DEN090007	Substantially Equivalent Both the proposed and predicate device hydrogel plug are designed to resorb over time, however they have different degradation time periods. The GLP animal study with the proposed and predicate devices demonstrates that the resorption for the proposed device is acceptable and there are no new or different questions in relation to safety and effectiveness.
Hydrogel Plug – Marking function	The hydrogel plug provides a marking function.	The hydrogel plug provides a marking function.	Same (Substantially Equivalent) Both the proposed and predicate device include a hydrogel plug that is visible under CT and can provide a marking function. GLP animal testing on the proposed and

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
			predicate devices demonstrated the plug marking function.
Materials – Hydrogel	The proposed hydrogel is composed of gelatin, hyaluronic acid and saline. The hydrogel is housed in a glass syringe and is provided in a hydrated, ready-to-use state. The prefilled hydrogel syringe is assembled with a polymer plunger rod, plunger stopper and backstop to facilitate delivery of the hydrogel from the syringe. The materials for the proposed device are medical device materials which meet the applicable requirements of ISO 10993-1.	The predicate hydrogel is composed of polyethylene glycol (PEG). The hydrogel plug is desiccated and housed in a coaxial adapter. It is hydrated on use with saline. The materials for the predicate are medical device materials which meet the applicable requirements of ISO 10993-1.	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness. Biocompatibility testing on the proposed device hydrogel demonstrated an acceptable biocompatibility profile.
Materials – delivery system	The proposed delivery system consists of a delivery needle assembly, including a stainless steel delivery needle and introducer needle with polymer hubs. A polymer depth marker ball is provided which sits on the introducer and may be used as a depth indicator. The materials for the proposed device are medical device materials which meet the applicable	The materials for the predicate are medical device materials which meet the applicable requirements of ISO 10993-1.	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness. Biocompatibility testing on the proposed device delivery system demonstrated an acceptable biocompatibility profile.

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
	requirements of ISO 10993-1.		
Chemical Composition - Hydrogel	The proposed hydrogel is composed of gelatin, hyaluronic acid and saline. The hydrogel is housed in a borosilicate glass syringe and is provided in a hydrated, ready-to-use state. The prefilled hydrogel syringe is assembled with a polysulfone plunger rod, elastomer plunger stopper and polysulfone backstop to facilitate delivery of the hydrogel from the syringe.	The predicate hydrogel is composed of polyethylene glycol (PEG). The hydrogel plug is desiccated and housed in a coaxial adapter composed of nylon. The hydrogel is hydrated on use with saline.	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness. Biocompatibility testing on the proposed device hydrogel demonstrated an acceptable biocompatibility profile.
Chemical composition – delivery system	The proposed delivery system consists of a delivery needle assembly, including a stainless steel delivery needle with a nylon12 hub and a stainless steel introducer needle with a polycarbonate hub. A pebax depth marker ball is provided which sits on the introducer and may be used as a depth indicator.	The materials for the predicate are medical device materials which meet the applicable requirements of ISO 10993-1	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness. Biocompatibility testing on the proposed device delivery system demonstrated an acceptable biocompatibility profile.
Biocompatibility – Hydrogel	The proposed device hydrogel is categorized as a implant medical device with long-term exposure (>30 days i.e. permanent) tissue contact.	The predicate hydrogel is categorized as a implant medical device with long-term exposure (>30 days i.e. permanent) tissue contact.	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness.

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
	The proposed device contains standard medical device materials which meet the applicable requirements of ISO 10993-1.	The proposed device contains standard medical device materials which meet the applicable requirements of ISO 10993-1.	Biocompatibility testing on the proposed device hydrogel demonstrated an acceptable biocompatibility profile.
Biocompatibility – Delivery System	The proposed device delivery system is categorized as an externally communicating medical device with limited (<24 hour) tissue contact. The Depth Marker Ball is categorized as a surface-contacting medical device with limited breached or compromised (<24 hour) surface contact. The proposed device contains standard medical device materials which meet the applicable requirements of ISO 10993-1.	The predicate device coaxial adapter and delivery system is categorized as an externally communicating medical device with limited (<24h) tissue contact device. The proposed device contains standard medical device materials which meet the applicable requirements of ISO 10993-1.	Substantially Equivalent Both the proposed and predicate device use standard medical device materials which meet the applicable requirements of ISO 10993-1, there is no impact to safety or effectiveness. Biocompatibility testing on the proposed device delivery system demonstrated an acceptable biocompatibility profile.
Sterility - Hydrogel	Sterile single-patient use The proposed device (prefilled hydrogel syringe) is sterilised using steam (moist heat) (Est A) to ensure a Sterility Assurance Level (SAL) of 10-6. The sterilization cycle was validated using the Overkill approach (half cycle method) per ISO 17665:2024.	Sterile single-patient use The predicate device (including hydrogel) is sterilized via exposure to the ethylene oxide (EO) gas sterilization process to ensure a Sterility Assurance Level (SAL) of 10-6. Per DEN090007, this process was validated in conformance with	Same (Substantially Equivalent) Both the proposed and predicate device hydrogels are sterilized to ensure a Sterility Assurance Level (SAL) of 10-6.

Proposed Pre-B. Seal Lung Biopsy Plug System to Predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007)			
Characteristic	**The Pre-B. Seal Lung Biopsy Plug System [Proposed device]**	**Primary Predicate Bio-Seal Lung Biopsy Tract Plug System [Primary Predicate] (DEN090007)**	**Comparison**
		consensus standard ISO 11135:1994	
Sterility - Delivery System	Sterile single-patient use The proposed device (delivery system) is sterilized via exposure to ethylene oxide (EO) gas sterilization process to ensure a Sterility Assurance Level (SAL) of 10-6. This process was validated using the Overkill approach (half cycle method) per ISO 11135: 2014.	Sterile single-patient use The predicate device (including the delivery system) is sterilized via exposure to the ethylene oxide (EO) gas sterilization process to ensure a Sterility Assurance Level (SAL) of 10-6. Per DEN090007, this process was validated in conformance with consensus standard ISO 11135:1994.	Same (Substantially Equivalent) Both the proposed and predicate device hydrogels are sterilized to ensure a Sterility Assurance Level (SAL) of 10-6.
Principles of Operation	The proposed device has been designed for sealing pleural punctures before the lung biopsy procedure is conducted. Sealing is achieved by delivering a biodegradable hydrogel sealant plug to below the surface of the lung through a delivery system. The hydrogel plug surrounds the delivery system during the lung biopsy procedure and remains in place after the delivery system has been withdrawn to fill the void created as part of performing the biopsy. The hydrogel resorbs over time.	The predicate device has been designed for sealing pleural punctures after the lung biopsy is conducted. Sealing is achieved by delivering a biodegradable hydrogel sealant plug into the biopsy tract, below the surface of the lung. The plug is delivered through the biopsy introducer via the delivery system The hydrogel plug remains in place after the delivery system and biopsy introducer have been withdrawn to fill the void created as part of performing the biopsy. The hydrogel resorbs over time.	Substantially Equivalent

Table 2 below demonstrates how the Pre-B Seal Lung Biopsy Plus System meets the special controls related to the Classification Regulation: 21 CFR 878.4755 - Absorbable lung biopsy plug

Table 2: Pre-B Seal Lung Biopsy Plus System compliance with 21 CFR 878.4755 (Special Controls)

21 CFR PART 878 General and Plastic Surgery Devices, Subpart E - Surgical Devices, 878.4755 Absorbable lung biopsy plug	**Does the Pre-B Seal Lung Biopsy Plus System meet the special controls (Yes / No)**	**Compliance with the special controls is demonstrated through:**
Special control (1): The design characteristics of the device must ensure that the geometry and material composition are consistent with the intended use.	Yes	• Description and Principles of Operation • Device Design (covered through illustrations, Schematics and or Diagrams) • Performance Testing (Design Verification) • Usability Testing • GLP Animal Study
Special Control (2): Performance testing must demonstrate deployment as indicated in the accompanying labelling, including the indicated introducer needles, and demonstrate expansion and resorption characteristics in a clinically relevant environment.	Yes	• Performance Testing (Design Verification) • Usability Testing • GLP Animal Study • Instructions for Use
Special Control (3): In vivo evaluation must demonstrate performance characteristics of the device, including the ability of the plug to not prematurely resorb or migrate and the rate of pneumothorax.	Yes	• GLP Animal Study
Special Control (4): Sterility testing must demonstrate the sterility of the device and the effects of the sterilization process on the physical characteristics of the plug.	Yes	• Sterility of the device is met via the Sterilization Validation studies. ➢ With regard the Eto Sterilization Validation - The validation for the packaged delivery system was completed in accordance with ISO 11135:2014 ➢ With regard the Steam Sterilization Validation – The validation for the packaged delivery system was completed in accordance with ISO 17665:2024 • The effects of the sterilization process on the physical characteristics of the plug has

21 CFR PART 878 General and Plastic Surgery Devices, Subpart E - Surgical Devices, 878.4755 Absorbable lung biopsy plug	**Does the Pre-B Seal Lung Biopsy Plus System meet the special controls (Yes / No)**	**Compliance with the special controls is demonstrated through:**
		been demonstrated through: ➢ Performance Testing (Design Verification) ➢ Usability Testing ➢ GLP Animal Study
Special Control (5): Shelf-life testing must demonstrate the shelf-life of the device including the physical characteristics of the plug.	Yes	Shelf-life testing was performed to demonstrate the shelf-life of the device including the physical characteristics of the plug.
Special Control (6): The device must be demonstrated to be biocompatible.	Yes	Biocompatibility Testing
Special Control (7): Labelling must include a detailed summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. Labelling must include identification of compatible introducer needles.	Yes	The Pre-B. Seal Lung Biopsy Plug System Instructions For Use details a summary of the device-related and procedure-related complications pertinent to the use of the device and appropriate warnings. The Pre-B. Seal Lung Biopsy Plug System includes the coaxial delivery system. The delivery system is provided assembled with the introducer engaged with the delivery needle. The compatibility of the introducer and delivery needle is detailed within the delivery system labelling and the Instructions For Use. The Pre-B. Seal Lung Biopsy Plug System introducer compatibility with biopsy devices is detailed within the delivery system labelling and the Instructions For Use.

Non-Clinical Bench Testing

Non-Clinical Bench Testing was conducted on the Selio Medical Ltd Pre-B Seal Lung Biopsy Plug System [proposed device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the Bio-Seal Lung Biopsy Tract Plug System (DEN090007) [predicate device]. The following Verification Data was provided in support of the substantial equivalence (SE) determination.

Table 3: Performance Data

Test	Consensus Standard/FDA Guidance/Description
Bench testing, including **Prefilled Hydrogel Syringe:** 1) Injection Force 2) Hydrogel physical characteristics 3) Dose and Volume 4) Visual inspection **Delivery System** 1) Component compatibility 2) Tensile test of bonds 3) ISO 80369-7 compliance 4) Leak test 5) Depth Marker Ball force 6) Visual Inspection 7) Insertion & Withdrawal force 8) Simulated use 9) Component Dimensional verification 10) Hub Detachment 11) Device compatibility with Biopsy Needle	• Confirm that the device meets intended product specifications. • All testing performed successfully, no questions regarding safety and effectiveness recorded, thus supporting that the proposed device is substantially equivalent to the predicate device.
Sterility Testing	
Test	**Consensus Standard/FDA Guidance/Description**
Sterility	• The Delivery System is sterilized via exposure to the ethylene oxide (EO) gas sterilization process to ensure a Sterility Assurance Level (SAL) of 10-6. This process was appropriately validated in conformance with consensus standard ISO 11135:2014. • The Prefilled Hydrogel Plug is sterilized via exposure to the steam (moist) sterilization process to ensure a Sterility Assurance Level (SAL) of 10-6. This process was appropriately validated in conformance with consensus standard ISO 17665:2024. All testing performed successfully, no questions regarding safety and effectiveness recorded, thus

	supporting that the proposed device is substantially equivalent to the predicate device.
Biocompatibility Testing	
Test	**Consensus Standard/FDA Guidance/Description**
Biocompatibility	• FDA Final Guidance Document, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and Testing within a risk management process" (September 2023) • ISO 10993-1: 2018, Biological Evaluation of Medical Devices, Part 1: Evaluation and testing within a risk management process. • **Test Results Passed**. The results of the Biocompatibility Testing conducted on the Selio Medical, Pre-B Seal Lung Biopsy Plug System [proposed device] demonstrates that the proposed device is biocompatible.
Usability Testing	
Test	**Consensus Standard/FDA Guidance/Description**
Usability Evaluation	• FDA Final Guidance Document, "Applying Human Factors and Usability Engineering to Medical Devices" (February 2016) • **Test Results Passed.** All critical tasks were successfully and safely performed without issue and all acceptance criteria were met. No new hazards, hazardous situations, hazard related use scenarios or risks were identified during the study. The study demonstrated that the device is both safe and effective for its intended users, uses, and use environments.

Non- Clinical Data (Animal Testing)

Non-Clinical Testing was conducted on the Selio Medical Limited Pre-B Seal Lung Biopsy Plug System [proposed device] to confirm that the device meets all system requirements and is substantially equivalent (SE) to the Bio-Seal Lung Biopsy Tract Plug System (DEN090007) [predicate device]. The following In Vivo GLP animal data was provided in support of the substantial equivalence (SE) determination.

Table 4: Non-Clinical Data

Animal GLP Study	
Test	**Consensus Standard/FDA Guidance/Description**
In Vivo GLP Animal Study	• FDA Final Guidance Document, "General Considerations for Animal Studies Intended to Evaluate Medical Devices" (March 2023) • Assess safety, performance and biocompatibility endpoints comparing the proposed Pre-B Seal Lung Biopsy System and the predicate Bio-Seal Lung Biopsy Tract Plug System in a swine model Assessment of Acute Usability and Performance: • Device and hydrogel plug visibility • Device positioning, plug deployment and deployment accuracy • Expansion / Resorption Characteristics • Biopsy needle insertion and ease of biopsy • Compatibility of device with biopsy device • Quality of lung biopsy sample Assessment of Safety: • Incidence of pneumothorax • Hydrogel plug migration, degradation / resorption • Hydrogel pulmonary embolization, systemic embolization • Pulmonary thromboembolism, Systemic thromboembolism • Bacterial colonization • Biocompatibility: local effects and systemic. • Overall animal health The GLP animal study demonstrated that the Selio Medical, Ltd. Pre-B Seal Lung Biopsy Plug System

	[proposed device] is substantially equivalent to the Bio-Seal Lung Biopsy Tract Plug System (DEN090007) [predicate device]. The data from this study demonstrated that the performance characteristics, including the ability of the plug to not prematurely resorb or migrate, of the Pre-B. Seal Lung Biopsy Plug System were acceptable. The rate and severity of pneumothorax was less than the predicate device.

Clinical Testing

Per pre-submission correspondence with the FDA no clinical data was required as Selio Medical have demonstrated through the non-clinical bench data (Design Verification bench data, Sterility, Biocompatibility, Usability) and animal test data, that the proposed device successfully meets its intended use, does not introduce new risks and has been demonstrated as safe and effective.

Conclusions:

It is concluded that the Selio Medical, Ltd. Pre-B Seal Lung Biopsy Plug System [proposed device] is substantially equivalent to the predicate Bio-Seal Lung Biopsy Tract Plug System (DEN090007) based on:

- Verification results related to performance (performance testing, sterilization testing, biocompatibility testing, usability testing).
- Results from a comparative GLP animal study of the proposed and predicate devices.
- These results demonstrate that the proposed device is as safe, as effective and performs as well as the predicate device that is currently marketed for the same intended use.
- Side-by-side comparison of the technological characteristics of design, indication for use / intended use, components, and materials of construction.
- The Pre-B. Seal Lung Biopsy Plug System meets the special controls outlined in Classification Regulation: 21 CFR 878.4755 - Absorbable lung biopsy plug.