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Premarket Registration Full Evaluation Route
Summary Assessment Report for
Changchun SinoBiomaterials LÖVISELLE® Poly-L-Lactic Acid Facial Filler

Listing number	MDPR260122Y0004
Date of approval	23/01/2026
Product owner	Changchun SinoBiomaterials.Co., Ltd.
Registrant	SINOBIOM (SINGAPORE) PTE. LTD.
Risk Class	Class D
Intended use / Indications of use	LÖVISELLE is suitable for increasing volume in depressed areas (of nasolabial folds and cheeks) for correcting skin depressions, skin creases, wrinkles, folds, scars, and signs of skin aging. LÖVISELLE is also indicated for large-volume facial corrections of the signs of facial fat loss (lipoatrophy).

1. Device description

LÖVISELLE is an injectable implant supplied as a sterile non-pyrogenic lyophilized powder that is reconstituted before injection with 0.9% sodium chloride injection. It is supplied in a glass vial and sterilised using irradiation. The product is not supplied with any accessories. LÖVISELLE is for single patient and single session use only.

The LÖVISELLE suspension contains microspheres of poly-L-lactic acid, a biocompatible, biodegradable, synthetic polymer from the alpha-hydroxy-acid family. The microspheres have a uniform particle size and degrade slowly. Reconstituted LÖVISELLE has a viscosity suitable for injection with a 26G needle into the deep dermis or the subcutaneous layer.

LÖVISELLE comes in three variations and each vial of dry powder for reconstitution contains:

1) 340mg/vial: Poly-L-lactic acid (150mg), Sodium carboxymethylcellulose (45mg), Mannitol (145mg)
2) 170mg/vial: Poly-L-lactic acid (75mg), Sodium carboxymethylcellulose (22.5mg), Mannitol (72.5mg)
3) 85mg/vial: Poly-L-lactic acid (37.5mg), Sodium carboxymethylcellulose (11.25mg), Mannitol (36.25mg)

LÖVISELLE is to be administered by appropriately trained healthcare professionals only. Additional contraindications, warnings and precautions can be found in the product labelling.

2. List of standards applied

Standards	Title
ISO 13485:2016	Medical devices — Quality management systems — Requirements for regulatory purposes
ISO 14971:2019	Medical devices — Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices — Guidance on the application of ISO 14971
ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part I : General requirements
ASTM F1980-21	Standard guide for accelerated aging of sterile barrier systems for medical devices
ISO 10993	Biological evaluation of medical devices
ISO 14630:2024	Non-active surgical implants — General requirements
ISO 11137-1:2025	Sterilization of health care products — Radiation —Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
ISO 11137-2:2013	Sterilization of health care products — Radiation —Part 2: Establishing the sterilization dose
ISO 13781:2017	Implants for — Homopolymers, copolymers and blends on poly(lactide) — In vitro degradation testing
EU PHARMACOPOEIA 11.0	EU PHARMACOPOEIA 11.0
ASTM F1925-24	Standard specification for semi-crystalline Poly(lactide) polymer and copolymer resins for surgical implants
ASTM D4603-18	Standard test method for determining inherent viscositv of Poly(Ethvlene Terephthalate) (PET) by glass capillary viscometer
ASTM F2347-24	Standard guide for characterization and testing of hyaluronan as starting materials intended for use in biomedical and tissue engineered medical product application
ICH Harmonised Guideline	Impurities: Guideline for residual solvents Q3C(R9)
USP <1207.2>	Package integrity leak test technologies

3. Pre-clinical assessment

(i) Cytotoxicity, sensitization, irritation/intracutaneous reactivity, systemic toxicity (acute), pyrogenicity, subacute and subchronic toxicity, genotoxicity, and implantation testing were done in accordance with ISO 10993 and passed.

(ii) Device is radiation sterilized in accordance with ISO 11137 and met sterility assurance level of 10^{-6}.

(iii) Studies (functional and packaging) provided supported shelf life of 3 years at room temperature, covering aspects of PLLA content, intrinsic viscosity, polydispersity, product appearance, sterility, self-sealing of rubber stopper and packaging appearance. Reconstitution stability study provided supports the claim of 72 hours at room temperature. Parameters tested include pH, mass loss rate, intrinsic viscosity and sterility.

(iv) Summary of bench testing: in vitro degradation study, appearance check, content uniformity, particle size distribution, particle size, osmolarity, extrusion force (using 26g needle), sterility and bacterial endotoxin tests were done and passed. Chemical performance tests were performed according to EU Pharmacopoeia 11.0 and passed.

4. Clinical assessment

(i) Literature review:

Summary: The overall quality of the literature discussed is acceptable in terms of the study design and sample size. In summary, the literature review is adequate and provides objective clinical experience of the equivalent and subject devices in increasing volume in depressed areas (of nasolabial folds and cheeks) for correcting skin depressions, skin creases, wrinkles, folds, scars, and signs of skin aging and large-volume facial corrections of lipoatrophy. The literature data, which encompassing a total sample size of more than 5000 patients with follow-up periods ranging from 2 months to 3 years, demonstrated acceptable safety and performance profiles of the devices based on the assessment of clinical outcomes and adverse events reported.

(ii) Evaluation of Clinical Investigations

Title	A Multicenter, Randomized, Parallel-Controlled Clinical Trial to Evaluate the Safety and Efficacy of Poly-L-lactic Acid Facial Filler in the Correction of Nasolabial Fold Wrinkles
Study Design	Multicenter, randomized, parallel-controlled Treatment group (Changchun SinoBiomaterials Poly-L-Lactic Acid Facial Filler) Control group (Injectable Modified Sodium Hyaluronate Gel)
Sample Size	188 subjects with moderate-to-severe nasolabial fold wrinkles (94 in treatment group, 94 in control group)
Follow-Up Period	48 weeks after final injection
Study Endpoints	**Primary Efficacy Endpoint:** Effective rate of correction of nasolabial fold wrinkles at 48 weeks post-treatment, based on the percentage of subjects in the treatment and control groups with a Wrinkle Severity Rating Scale (WSRS) score improvement of more than 1 grade on both sides of the nasolabial folds compared to baseline **Secondary Efficacy Endpoints:**

	1) The percentage of subjects with a WSRS score improvement of more than 1 grade in nasolabial fold wrinkles at 24 weeks post-correction compared to baseline. 2) Investigator and subject global aesthetic improvement assessments (GAIS) at 24 and 48 weeks post-correction. **Safety:** Occurrence of adverse events.
Study Device	Changchun SinoBiomaterials Poly-L-Lactic Acid Facial Filler
Efficacy results	**Primary Efficacy Endpoint:** At Week 48, the treatment group showed a significantly higher WSRS effectiveness rate than the control group, with the lower limit of the 95% CI exceeding 0, thereby confirming superiority. These results demonstrated that the subject device was clinically more effective than the control device in improving moderate to severe nasolabial folds. **Secondary Efficacy Endpoints:** Across all secondary endpoints including WSRS effectiveness rates at Weeks 24 and 48 and GAIS scores at Weeks 6, 24, and 48, the treatment group demonstrated statistically significant superiority over the control group.
Safety results	All 188 subjects with moderate-to-severe nasolabial fold wrinkles were included in the safety analysis. The incidence of adverse events (AEs) deemed related to the subject device was 17.55%, primarily involving general disorders and administration site conditions which accounted for 15.43%. Follow-up data indicated that all adverse events related to the subject device had resolved by 48 weeks. A total of 4 serious adverse events (SAEs) occurred in the treatment group. No SAEs were deemed related to the subject device.
HSA's assessment	The overall quality of the clinical study is acceptable in terms of design and sample size. The data supports the performance and safety of the subject device in correction of nasolabial fold wrinkles WSRS effectiveness and both investigator and subject GAIS scores were significantly higher in the treatment group. All adverse events observed were consistent with those reported in literature and the State of the Art (SOTA) and are reflected in the IFU.

Assessment:

Overall, the data derived from the clinical investigation and literature supports the full scope of LÖVISELLE's indications. The clinical investigation further demonstrated that the treatment group was more effective than control group across all primary and secondary efficacy endpoints.
In conclusion, it provides adequate clinical evidence to support the safety and performance of the subject device in increasing volume in depressed areas (of nasolabial folds and cheeks) for correcting skin depressions, skin creases, wrinkles, folds, scars, and signs of skin aging and large-volume facial corrections of lipoatrophy.

Clinical experience:

No device-related adverse events or field safety corrective actions associated with the use of the device were reported in the post-market surveillance assessment conducted by the product owner.

5. Assessment of device quality

The device is manufactured and sterilized in China at Changchun SinoBiomaterials Co., Ltd., Jilin Zhonghe Irradiation Co., Ltd. and CGN Irradiation Technology Co., Ltd. All manufacturing and sterilization sites conform to ISO 13485:2016 Quality Management System.

6. Conclusion

The LÖVISELLE® Poly-L-Lactic Acid Facial Filler demonstrates acceptable safety and performance for its intended use of increasing volume in depressed areas (of nasolabial folds and cheeks) for correcting skin depressions, skin creases, wrinkles, folds, scars, and signs of skin aging and large volume facial correction of lipoatrophy. All foreseeable risks have been systematically identified and mitigated through appropriate design controls, comprehensive labelling, and detailed user instructions. The preclinical and clinical data substantiate the device's safety and effectiveness for the intended patient population.