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Premarket Registration Full Evaluation Route
Summary Assessment Report for
Sonosemi LiqMagic C14 Coronary Intravascular Lithotripsy Catheter

Listing number	MDPR260521C0005
Date of approval	21/05/2026
Product owner	Sonosemi Medical Co., Ltd.
Registrant	EMERGO Singapore Consulting Pte Ltd
Risk Class	Class D
Intended use / Indications of use	The device is used in medical institution, with the Intravascular Lithotripsy Generator which manufactured by Sonosemi Medical, intended for pretreatment and balloon dilation of calcified, de novo stenotic coronary arteries in adult patients prior to stenting.

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1. Device description

The Sonosemi LiqMagic C14 Coronary Intravascular Lithotripsy Catheter is a sterile, single-use active device for pretreatment and balloon dilation of calcified, de novo stenotic coronary arteries in adult patients prior to stenting. It consists of a balloon incorporating two emitters, a catheter shaft, a catheter hub and a connector.

During use, the balloon is filled with saline and connected to the Sonosemi Intravascular Lithotripsy Generator. Electrical discharge vaporizes fluid between the electrodes and produces acoustic pressure waves. The waves selectively fracture superficial and deep calcium in vessel walls while minimizing trauma to soft tissue; calcium fragments remain in situ. All device operations are performed under appropriate X-ray fluoroscopy.

The device is available in seven models, with balloon diameters from 2.50 mm to 4.00 mm in 0.25 mm increments, a 12 mm balloon length, a maximum of 100 pulses and a 1400 mm working length.

The catheter is supplied sterile following ethylene oxide sterilization and is for single use by appropriately trained healthcare professionals. Additional contraindications, warnings, precautions and adverse effects can be found in the product labelling

2. List of standards applied

Standards	Title
EN ISO 13485:2016+A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes
EN ISO 14971:2019/A11:2021	Medical devices - Application of risk management to medical devices
ISO/TR 24971:2020	Medical devices - Guidance on the application of ISO 14971
EN ISO 10555-1:2023	Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements
EN ISO 10555-4:2023	Intravascular catheters - Sterile and single-use catheters - Part 4: Balloon dilatation catheters
EN ISO 80369-7:2021	Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications
EN ISO 10993 series	Biological evaluation of medical devices (Parts 1, 4, 5, 7, 10, 11, 17, 18 and 23)
EN ISO 11135:2014+A1:2019	Sterilization of health-care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices
EN ISO 11607-1:2020+A1:2023	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
EN ISO 11607-2:2020+A1:2023	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes
EN ISO 11737-1:2018+A1:2021	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products
EN ISO 11737-2:2020	Sterilization of health care products - Microbiological methods - Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
ISO 14644-1:2015 / ISO 14644-2:2015	Cleanrooms and associated controlled environments - Classification and monitoring of air cleanliness by particle concentration
ASTM D4169-22	Standard practice for performance testing of shipping containers and systems
IEC 60601-1:2005+A1:2012+A2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2:2014+A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Electromagnetic disturbances - Requirements and tests
IEC 62366-1:2015+A1:2020 / IEC/TR 62366-2:2016	Medical devices - Application of usability engineering and related guidance
EN ISO 14155:2020	Clinical investigation of medical devices for human subjects - Good clinical practice

3. Pre-clinical assessment

(i) Cytotoxicity, sensitization, irritation/intracutaneous reactivity, material-mediated pyrogenicity, acute systemic toxicity, hemocompatibility testing, chemical characterization and toxicological risk assessment were done in accordance with EN ISO 10993 and passed.

(ii) The device is ethylene oxide sterilized in accordance with EN ISO 11135 and met sterility assurance level of 10^{-6}. EO and ECH residuals met EN ISO 10993-7 requirements.

(iii) Shelf life of 2 years is supported by real-time aging studies. Functional testing covered the catheter aspects of: appearance and distal tip, balloon crossing profile, dimension, hydration, peak tensile force, freedom from leakage, catheter hub, balloon rated burst pressure, balloon fatigue, balloon inflation and deflation times, balloon compliance, hydrophilic coating integrity (appearance), hydrophilic coating integrity (particle shedding), hydrophilic coating friction, hydrophilic coating firmness, simulated use, balloon removal, particulate matter, number of pulse discharge, electrical safety, acoustic output performance. Product functional performance and packaging integrity met the acceptance criteria.

(iv) Summary of bench testing: appearance and distal tip, balloon crossing profile, dimension, hydration, corrosion resistance, peak tensile force, freedom from leakage, catheter hub, x-ray detectability, balloon rated burst pressure, balloon fatigue, balloon inflation and deflation times, balloon compliance, hydrophilic coating integrity (appearance), hydrophilic coating friction, hydrophilic coating firmness, simulated use, balloon removal, particulate matter, number of pulse discharge, temperature rise test, acoustic output performance and hydrophilic coating integrity (particle shedding) were done and passed.

(v) In addition, electrical safety, electromagnetic compatibility, generator compatibility and combination use, formative and summative usability evaluations and animal studies were also completed. All tests conducted 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 similar devices and subject device for the pretreatment and balloon dilation of calcified, de novo stenotic coronary arteries in adult patients prior to stenting. The literature data demonstrated that the subject device was comparable to the current golden standard treatment device in terms of safety and performance.

(ii) Evaluation of Clinical Investigations

Title	CALCI-CRACK trial: To confirm the safety and effectiveness of Sonosemi Medical Coronary Intravascular Lithotripsy System for the treatment of severely calcified, stenotic primary coronary lesions prior to stenting.
Study Design	Prospective, multicenter, single-arm objective performance criteria clinical investigation

Sample Size	242 subjects with severe coronary calcification, including 93 subjects in the optical coherence tomography (OCT) subgroup.
Follow-Up Period	30 days and 6 months.
Study Endpoints	**Primary Efficacy Endpoints:** Procedural success, defined as stent delivery with residual stenosis ≤30% and without in-hospital major adverse cardiac events, MACE (cardiac death, myocardial infarction or target vessel revascularization). **Secondary Efficacy Endpoint:** Angiographic success, defined as stent delivery with ≤30% residual stenosis and without serious angiographic complications. **Secondary Safety Endpoints:** MACE-free rate at 30 days and 6 months, device crossing success and serious angiographic complications. **OCT Sub-study Secondary Endpoints:** Acute minimal stent area (MSA) and acute minimal lumen diameter (MLD) after the procedure.
Study Device	Sonosemi Coronary Intravascular Lithotripsy Catheter, used with Intravascular Lithotripsy Generator model SI-SH001-01.
Efficacy results	**Primary Endpoint:** Procedural success was 95.04% (230/242; 95% CI 91.50%–97.41%). The lower limit of the confidence interval exceeded the performance target of 83.4% ($p < 0.001$), confirming that the primary endpoint was met. **Secondary Endpoints:** Angiographic success was 98.35% (238/242) and device success was 98.52%. Serious angiographic complications occurred in 0.42% (1/240). In the OCT subgroup, the mean acute minimal stent area was 4.91 ± 1.22 mm², the mean acute minimal lumen diameter was 2.26 ± 0.35 mm and the stent expansion rate was 71 ± 12%.
Safety results	MACE-free at 30 days was 95.87% (232/243) and MACE-free at 6 months was 95.45% (231/242). MACE incidence was 1.65% during the procedure, 4.13% before discharge and at 30 days, and 4.55% at 6 months. Target lesion failure was 1.24% at 1 month and 1.65% at 6 months. A total of 300 adverse events were recorded, of which 6 were device-related and 29 were serious. • All 6 device-related adverse events were non-serious. • None of the serious adverse events, including the 1 death reported, were related to the investigational device. • Overall, no device deficiencies were reported.
HSA's assessment	The clinical investigation conducted met the primary and secondary endpoints. The study design, sample size, endpoints and follow-up were acceptable for the intended use. Procedural success, angiographic success and safety outcomes were consistent with the state-of-the-art (SOTA) ranges. The data supports the safety and performance of the subject device for pretreatment and balloon dilation of calcified, de novo stenotic coronary arteries prior to stenting.

Assessment: Overall, clinical investigation and literature provide adequate clinical evidence to support the intended use of the Sonosemi LiqMagic C14 Coronary Intravascular Lithotripsy Catheter. The clinical investigation met its primary and secondary endpoints, and the clinical safety and performance results were consistent with the current state of the art. In conclusion, the available evidence supports a positive benefit-risk profile when the device is used according to the instructions for use.

Clinical experience:

Post-market surveillance covered more than 6,000 units supplied from December 2023 to July 2024. Two complaints were received; both were attributed to user error, were not device-related and were resolved through training. No post-market adverse events, recalls, vigilance actions or field safety corrective actions were reported.

5. Assessment of device quality

The devices are manufactured in China at Sonosemi Medical Co., Ltd. and ethylene oxide sterilized at Dongguan King Medical Technology Co., Ltd. All manufacturing and sterilization sites conform to EN ISO 13485:2016 Quality Management System.

6. Conclusion

The Sonosemi LiqMagic C14 Coronary Intravascular Lithotripsy Catheter demonstrates acceptable safety and performance for its intended use of pretreatment and balloon dilation of calcified, de novo stenotic coronary arteries in adult patients prior to stenting. The applicable pre-clinical testing and clinical data substantiate the device's safety and effectiveness. Known and foreseeable risks have been systematically identified, controlled and mitigated. Residual risks are acceptable when weighed against the clinical benefits, and relevant precautions and adverse effects are communicated through product labelling and instructions for use.