

Additional list of questions and answers from the webinar held on June 24, 2025

1. How long does FDA registration take, and how does it compare to MDR?

Registering a medical device with the FDA under the 510(k) pathway typically takes between 6 to 12 months, assuming well-prepared documentation and no significant objections from the regulator. In comparison, obtaining CE certification under the MDR in the European Union can take as long as 18 to 30 months. This is due to the requirement for comprehensive clinical investigations, evaluation by a notified body, and meeting post-market surveillance obligations. In terms of time and predictability, the FDA pathway is significantly more efficient.

2. Why did Medinice choose the 510(k) pathway, and were clinical trials necessary?

Medinice chose the 510(k) pathway because the CoolCryo technology was classified as substantially equivalent to existing predicate devices previously approved by the FDA. As a result, there was no need to conduct new clinical trials in the United States. The submission included technical data, preclinical testing results, validation outcomes, and a comparative analysis with reference products.

3. Which FDA procedures is Medinice using and why?

The company used the 510(k) procedure, which is intended for Class II devices that have technological equivalents already available on the U.S. market. This pathway was chosen due to its lower costs, shorter registration timeline, and the ability to avoid full clinical trials. The De Novo procedure, which is used for entirely novel solutions, was not required because predicate devices were available for CoolCryo.

4. How does the FDA differ from the MDR?

The FDA allows medical device registration based on substantial equivalence to an already approved device, which can enable market entry without conducting clinical trials. In contrast, the MDR, which applies in the EU, typically requires full clinical studies, the development of a comprehensive Clinical Evaluation Report (CER), and approval by a notified body. Additionally, the MDR imposes broader requirements for post-market surveillance (PMS) and post-market clinical follow-up (PMCF).

5. Is the FDA more innovation-friendly than the MDR?

From a manufacturer's perspective, the FDA is considered a more innovation-friendly regulatory body. It allows for early consultations (pre-submission) and offers pathways such as 510(k), De Novo, and the Breakthrough Device Program, which help tailor the regulatory strategy to the specific type of technology. In contrast, the MDR in Europe is more formalized, often more expensive, and can significantly delay the market introduction of innovative products.

6. How much lower are the FDA pathway costs, and how does this affect the margin?

Registration with the FDA under the 510(k) pathway costs approximately \$300,000 to \$700,000. In contrast, the MDR pathway often involves expenses of €1.5 to €3 million, primarily due to the requirement for clinical trials and involvement of a notified body. The lower registration costs make the project more attractive to potential commercial partners and enable a higher gross margin for the licensee.

7. How long did documentation prep take, and when is the decision expected?

It took Medinice approximately 12 months to prepare the documentation, which included validation testing, comparative analysis, technical documentation, and quality system elements. The 510(k) submission was filed in June 2025. The company expects an FDA decision within 6 to 12 months, no later than mid-2026.

8. What is the commercialization strategy and what are the partnership plans?

Medinice's strategy is based on licensing the CoolCryo technology or entering into a partnership agreement with a company experienced in the manufacturing and distribution of medical devices. The company is open to both regional and global licensing deals. The final form of cooperation will depend on the market structure and the profile of the partner.

9. Was choosing the U.S. as the first market a strategic decision, and what's next?

The decision to begin the registration process in the U.S. was entirely strategic. The 510(k) pathway offers faster and more predictable market access compared to the MDR. After obtaining FDA clearance, Medinice plans to adapt the documentation for MDR compliance and initiate discussions with commercial partners for entry into the EU market and other countries that recognize FDA approval.

10. How will FDA certification impact market entry in the U.S.?

Obtaining FDA clearance will significantly increase the value of the project and its attractiveness to companies interested in commercializing CoolCryo. It will pave the way for signing a licensing or distribution agreement with an industry partner responsible for bringing the product to the U.S. market.

11. What are the key milestones for the next 12–24 months?

The main objective is to obtain FDA clearance by mid-2026. In parallel, Medinice plans to prepare the regulatory package for MDR and begin licensing negotiations. Additional milestones include signing a commercial agreement and preparing CoolCryo for implementation by a partner in international markets.

12. Biggest challenges in certification prep – and how were they solved?

The biggest challenge was meeting FDA requirements regarding technical documentation, validation, and conformity with the predicate device. Medinice formed a cross-functional team and collaborated with experienced regulatory affairs advisors, which enabled the company to successfully complete the preparations and submit the documentation on time.

13. How is the production infrastructure prepared for higher demand?

Medinice does not operate its own manufacturing facilities. Instead, it has developed the technological and quality documentation to enable an industrial partner to efficiently start serial production in compliance with FDA regulations and ISO 13485. The technology is fully ready for transfer to a manufacturing partner.

14. Did you work with regulatory affairs consultants, or was everything done in-house?

The process was carried out using a hybrid model. Medinice developed the key elements of the documentation internally, while consultations with FDA-specialized regulatory affairs advisors supported risk assessment, compliance verification, and preparation of documents in line with current guidelines.

15. What are CoolCryo's clinical benefits from a physician's perspective?

From a physician's perspective, the main advantage of CoolCryo is the use of liquid nitrogen as the cooling agent, which enables significantly lower temperatures compared to standard systems. This results in a deeper and more precise ablation effect, potentially leading to more effective treatment and a lower risk of arrhythmia recurrence. The technology also offers improved procedural control and reduced procedure time, enhancing operator comfort and patient safety.

16. What technological innovations distinguish CoolCryo?

CoolCryo stands out with its closed-loop cooling system based on liquid nitrogen and a modern applicator designed for high-precision tissue contact. The system also features an advanced temperature and pressure control mechanism, allowing dynamic management of procedural parameters. The device has been optimized for ergonomics and seamless integration into the operating room environment.

17. What were the biggest technological challenges in developing CoolCryo?

The main challenge was ensuring the safe and precise handling of liquid nitrogen in a clinical environment. This required the development of a specialized applicator, proper thermal insulation, precise flow control, and compliance with technical standards for medical devices. The final solutions were achieved through numerous design iterations, testing phases, and close collaboration between engineering and clinical teams.

18. What is Medinice’s long-term vision after obtaining FDA certification?

Medinice aims to become a recognized international provider of medical technologies in the fields of electrophysiology and cryosurgery. FDA certification for CoolCryo is the first step toward broader commercialization and global expansion. The company plans to develop additional innovative projects, form strategic technology partnerships, and continue increasing the value of its portfolio.

19. How will FDA certification affect the company’s valuation and perception among investors?

Obtaining FDA approval is a pivotal milestone in the project’s lifecycle—it confirms the safety and quality of the technology while significantly increasing its market value. For investors, it marks the transition from the development phase to the commercialization phase. Such a milestone typically leads to greater interest from capital markets and enhances the company’s reputation as both a technology and investment partner.

20. Why aren’t the management team buying shares, despite believing the company is undervalued?

Company executives can only purchase shares outside of closed trading periods and provided they do not have access to insider information. In practice, management is often restricted from doing so due to ongoing regulatory processes or commercial negotiations. Medinice emphasizes that the most meaningful demonstration of the management’s commitment is the effective execution of its strategy and the continued growth in project value.

21. When will CoolCryo be available for clinical use, what will the price be, and what is the expected sales volume?

CoolCryo will be eligible for clinical use following FDA certification, which is expected by mid-2026. Market launch and commercialization will be the responsibility of the licensee or industrial partner, who will define the sales model, market pricing, and distribution scale. As a result, Medinice does not publish forecasts regarding the product’s price or sales volume.

22. Can an ESPI report regarding the joint venture be expected?

Yes, if decisions related to the joint venture have a material impact on the company’s financial situation, strategy, or valuation, they will be promptly disclosed in the form of a current ESPI report. Medinice fully complies with all disclosure obligations under MAR regulations and the rules of the regulated market.

23. Can CoolCryo be integrated with Adagio Medical’s device?

CoolCryo was designed as a standalone and technologically self-contained solution. Integration with systems from other manufacturers, such as Adagio Medical, is not envisioned. Any potential interoperability would require advanced technological collaboration, which Medinice is not pursuing at this stage.

24. When were the clinical studies involving 16 patients completed and post-operative reports prepared?

The clinical studies involving 16 patients were completed in the first quarter of 2025. Post-operative reports were then prepared, and the collected data was included in the regulatory submission filed with the FDA in June 2025. These data support the evaluation of the device's effectiveness and safety.

25. What is the timeline for CoolCryo's entry into the European market?

After obtaining FDA certification, Medinice plans to begin adapting the documentation to meet MDR requirements. This phase is expected to start in the second half of 2026. The registration process in the EU could be completed in 2027, depending on the notified body's requirements and the duration of the assessment procedure.