

Press Release 06-02 2025

FDA approves clinical product from MotilityCount

Only four months after receiving approval in the EU for a new clinical product from the Danish medtech company MotilityCount, the company has now also received the US FDA Clearance. With two of the most important regulatory approvals in the world, the path is paved for the global market.

The door has been opened to a wide range of markets for MotilityCount's major product, SwimCount® Harvester, which was developed by Danish specialists in fertility treatment. The Danish medtech company has just received a US FDA 510(k) Clearance, only four months after the company obtained a European Medical Device Regulation 2017/745 (EU MDR).

“These two regulatory approvals mark an exceptionally important milestone for MotilityCount. They confirm our ability to meet the highest standards in the healthcare industry and underline our commitment to bringing safe and innovative solutions to markets worldwide, where there is an increasing need for assistance within infertility. There is no doubt that these approvals enhance our credibility in the market, which may help accelerate local regulatory processes, says Mogens C. Thomsen, CEO of MotilityCount.

SwimCount® Harvester is a simple and safe method for sperm processing used in fertility treatments, including IUI (Intrauterine Insemination), IVF (In Vitro Fertilization), and/or ICSI (Intracytoplasmic Sperm Injection), aimed at gynecologists and fertility clinics. SwimCount® Harvester was launched successfully in Japan in 2024. Additionally, SwimCount® Harvester is now sold through distributors in countries such as Australia, Hong Kong, Germany, Austria, Denmark, Sweden, UAE, Oman, South Africa, and soon in Thailand, where MotilityCount has just received the local regulatory approval, Thai FDA Registration.

Soon, MotilityCount will also launch in the USA and other European countries (including Portugal, the Czech Republic, and Slovakia) as well as in Asia (specifically Singapore), where distribution agreements have been entered into, but local regulatory approvals are still pending.

Researcher: Danish product is groundbreaking

The new clinical product has received high praise. Researcher and fertility embryologist, Ph.D., Dr. Marcos Meseguer from the world-leading fertility group IVIRMA Global in Valencia, Spain, believes that SwimCount® Harvester has the potential to revolutionize the practices used by fertility clinics and laboratories for decades. He has conducted a clinical study* on SwimCount® Harvester for the past four years and says:

“For over 30 years, the traditional methods and Golden Standards for selecting sperm for fertilization in the laboratory have been Density Gradient Centrifugation (DGC) and Swim-up. SwimCount® Harvester performs essentially the same process but in a much simpler and more efficient way, and we are therefore looking at a real alternative. SwimCount® Harvester improves and automates sperm selection for fertilization. The quality of the sperm is significantly better in several areas than we have seen before. The process is simpler, reducing time consumption, costs, and the risk of human error in the laboratory.”

Overall, the sperm processing method can significantly impact a couple's chance of achieving a successful pregnancy. Particularly in difficult cases where the male partner struggles with low sperm quality and where fertility treatment is necessary to achieve pregnancy, the new method is of great interest, emphasizes Marcos Meseguer:



“The ability to improve sperm quality through a better selection process is always advantageous -especially in the most challenging cases. SwimCount® Harvester can make the treatment less invasive in some cases, for example, by using IUI treatment instead of IVF and ICSI.”

***Facts about the clinical study conducted by IVIRMA Global**

The clinical study of SwimCount® Harvester, mentioned in the press release and conducted by IVIRMA Global in Valencia, Spain, has been part of the European funding program Eurostars. Here, IVIRMA Global was part of the consortium that helped develop and test SwimCount® Harvester. The partnership is co-financed by the EU through Horizon Europe, a research, development, and innovation support program.

Contact:

Mathilde Forstholt, Press Contact, Tel: +45 6165 3065, mathilde@forstholt.com
CEO Mogens C. Thomsen, Tel: +45 4060 3303, mct@motilitycount.com

More information for the press is available at www.motilitycount.com
Press photos can be downloaded from www.motilitycount.com

Learn more about SwimCount® Harvester at www.swimcountharvester.com

About MotilityCount

MotilityCount ApS specializes in developing technologies and products for sperm analysis and microfluidic sperm processing.

In addition to SwimCount® Harvester, which is developed and produced 100% in Denmark, MotilityCount is behind the well-known pre-screening at-home test for men, SwimCount® Sperm Quality Test, which was launched in Europe in 2015. The test allows men to check their sperm quality in just 30 minutes, without the need first to visit a doctor or fertility clinic. The goal has been to make it easier for men to test whether they have normal or low sperm quality at an earlier stage. In 2019, the at-home test was launched in the USA, and it is sold under a US FDA 510(k) and a CE IVDR in Europe and other countries.

SwimCount® Sperm Quality Test has seen increasing sales to about 30 countries, including the USA, where the test is listed in CVS Pharmacy and Walgreens through the company’s exclusive importer and distributor, meaning that the product is sold in thousands of retail pharmacy stores across the United States.

MotilityCount is also behind the following brands: SwimCount™ SpermCare, PetCount™ Sperm Quality Test for Dogs, and VetCount™ Harvester.

MotilityCount is funded by Private Investors, the Danish Fund Welfare Tech Invest, and the Danish Export and Investment Fund (EIFO).

In addition to a clinical study of SwimCount® Harvester’s performance versus Density Gradient Centrifugation (DGC), researchers at IVIRMA Global are conducting an embryo quality study, where sperm processed with SwimCount® Harvester is used to fertilize eggs. Here, improved clinical results are also observed, as SwimCount® Harvester is performing 22.8% better than Swim-up, which is widely acknowledged today.

Further information about the clinical study from IVIRMA Global in Valencia, Spain can be found at www.swimcountharvester.com.