PRESS RELEASE
07 February 2023 12:40:00 CET

ProstaLund has received CE approval under MDR for its new treatment platform CoreTherm® Eagle

ProstaLund today announces that the company has received market approval from the certification body TÜV SÜD for its new platform CoreTherm® Eagle for benign prostatic hyperplasia (BPH / BPE) through a CE marking based on the EU medical device regulations (MDR).

CoreTherm® heat treatment is a fast, safe, and effective treatment for benign prostatic hyperplasia (BPH/BPE). The treatment takes less than 15 minutes without surgical intervention. A great advantage of the method is that the size of the prostate is not a limited factor and the prostate up to 366 ml has been treated. CoreTherm® is performed under local anesthesia and the patient thus avoids anesthesia and overnight stays in the hospital. The treatment is carried out at 27 clinics in the Nordic region and at a smaller number outside the Nordic region.

"This MDR certification is important in many aspects. It shows that we have a Technical Documentation that ensures the safety and performance of CoreTherm Eagle and also that we have a well-functioning quality system with good traceability and that we work methodically in well-defined processes.

The platform itself is a masterpiece and CoreTherm® is thus probably the world's best BPE treatment if you look at parameters such as treatment results, the ability to treat regardless of the size of the prostate, re-treatment frequency, treatment time, fewer complications compared to surgical procedures, learning time for treating doctors and the cost of a treatment, etc. We expect to start production in the third quarter of 2023", says CEO Johan Wennerholm in a comment.

About the MDR regulations

The new MDR regulatory framework (where MDR stands for Medical Device Regulation) is designed according to an EU regulation (2017/745) developed to ensure the safety and performance of medical devices. Compared to the previous MDD regulations, updates have been made on which medical devices may be on the market, as well as how to provide and use products. The MDR regulatory framework improves patient safety by introducing stricter methods of assessment and monitoring on the market. It also contains rules for how medical technology companies should carry out product evaluations within the EU. This ensures that unsafe and non-compliant products and equipment do not end up on the market. The MDR regulations cover all companies that sell medical devices to EU Member States, Switzerland, and member states within the EEA.

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About ProstaLund

ProstaLund AB is a Swedish medical technology company and a leading developer and manufacturer of innovative urological devices and treatments. The company's lead product, CoreTherm, is a patented Thermotherapy treatment method for Benign Prostatic Hyperplasia (BPH) which can be tailored to suit the needs of each individual patient. CoreTherm is used today in hospitals and clinics in Sweden and worldwide. ProstaLund is listed on the Nasdaq First North Growth Market.

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This information is information that ProstaLund AB (publ) is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-02-07 12:40 CET.

Attachments

ProstaLund has received CE approval under MDR for its new treatment platform CoreTherm® Eagle