

Press release 2022-03-01

NeoDynamics has filed for registration of NeoNavia® in the US

The MedTech company NeoDynamics has filed a registration application for its innovative pulse biopsy system NeoNavia® with the US Food and Drug Administration, FDA. The product already has CE approval in Europe and is in clinical use.

“By filing for registration of NeoNavia in the US, NeoDynamics reaches an important milestone. The US is a huge potential market for NeoNavia and a US registration is also an important seal of quality for future collaborations”, says CEO Anna Eriksrud. “We expect that it will take a number of months to get the registration application approved.”

The application, which is submitted after dialogue with the FDA, is filed in the form of a 510(k), which is a less complicated procedure than an application for a new drug. Once the product has received marketing approval, NeoDynamics intends to continue to work with clinics to document the product in clinical practice to support its marketing and sales strategy. Similar has been done in Europe successfully to demonstrate the benefits of the product, which have contributed to creating a broader interest around the NeoNavia system. In turn, this will develop long term relationships with physicians and facilitate sales.

NeoNavia is an innovative biopsy system that uses a patented pulse technology for controlled and accurate needle insertion, which is based on research at Karolinska Institutet. NeoDynamics’ goal is for the pulse technology to become the new standard for ultrasound-guided breast biopsies.

For further information, please contact:

Anna Eriksrud, CEO NeoDynamics AB, phone +46708 444 966 or e-mail anna.eriksrud@neodynamics.com

About NeoDynamics

NeoDynamics AB (publ) is a Swedish Medical Technology Company dedicated to advancing diagnosis and care of breast cancer. The company’s first product NeoNavia®, a new innovative pulse biopsy system for ultrasound guided tissue sampling, is currently being introduced to the market. The biopsy system is built on a patented pulse technology, based on research at the Karolinska Institutet in Sweden. NeoNavia is evaluated for breast cancer diagnosis at leading clinics in UK, Germany, and Sweden. The pulse biopsy system has been used for tissue sampling in breast and axilla in over 500 patients.

About NeoNavia

NeoNavia is a modern biopsy system with a completely new patented pulse technology intended for ultrasound-guided tissue sampling. It consists of a base unit, a handheld driver and three different types of biopsy needles. Each needle type is driven by the pulse technology providing a more controlled needle insertion and precise placement of the needle in the tumour whilst enabling high-quality tissue samples from both breasts and lymph nodes. The pulse biopsy system NeoNavia is designed to offer clinicians and patients accurate lesion targeting and high tissue yield for correct diagnosis and individualized treatment.