

PRESS RELEASE

PRIMAA ANNOUNCES CE-MARKING OF ITS IVDMD

A NEW MAJOR STEP FORWARD FOR THE EXPERT FRENCH START-UP IN PATHOLOGICAL DIAGNOSIS

PARIS, FRANCE (November 2021) – Primaa, a company specialized in developing artificial-intelligence based software for histological diagnoses, today announced the European launch of *Cleo Breast Cancer*. The CE-mark will allow Primaa's innovative solution to enter the European Union market and any other markets that accept CE-marking.

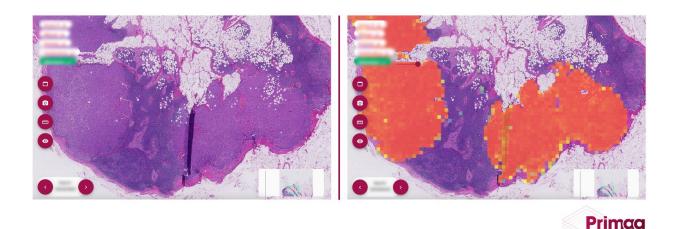
The need for innovative solutions in the pathology market around the world

With 250 million samples analyzed each year worldwide, the number of cancer diagnoses has almost doubled between 2000 and 2020, but the number of doctors has not increased at the same rate. As a result, pathology labs and hospitals are looking forward to new digital products to meet this growing demand.

"The workload is increasing, and the profession requires ever greater technical skills. There are departments in France where there are no pathologists at all. We must make up for this shortage in areas where access to diagnosis is difficult, which has the effect of delaying it. However, it is necessary to have a diagnosis in time, whereas the fight against cancer is a fight against time", explains Marie Sockeel, Primaa's pathologist and medical advisor.



About Cleo Breast Cancer



Cleo Breast Cancer is the first diagnostic tool for pathology using Artificial Intelligence. Designed with pathologists for pathologists, the algorithm works using proven machine learning and deep learning methods, and improves its sensitivity and specificity over time and with new data. After connecting to the scanner, the software automatically analyzes the digital slide and the results are displayed on a viewing tool showing the characteristics of breast cancer. The pathologist can then quickly validate the analysis. Pathology laboratories and hospitals can expect to save up to 40% of their time after deployment.

"Our goal with Cleo Breast Cancer was to develop a solution that seamlessly integrates into the pathologist's workflow, because a great solution implies a flawless user experience", replies Stéphane Sockeel, Primaa's Chief Technology Officer.

CE-Mark confirms Primaa's legitimacy

The CE-IVD marking is the result of 3 years of development in collaboration with French university hospitals and a clinical validation study of its solution. The breast solution is currently being implemented in several centers and the company is already considering the development of new organs.

"This marking is another evidence of the efficacy of our solutions and allows Primaa to continue to develop our solutions in compliance with the highest standards for safety, product performance and reliability", added Fanny Sockeel, Primaa's CEO.



About Primaa

Primaa is a medtech startup based in Paris, the objective of which is to develop diagnostic software based on artificial intelligence for histological diagnosis. A member of the BPI Excellence Program, it is supported by 50 Partners, Pleiade Ventures, and Angels Santé.

For more information, visit www.primaalab.com.

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