

# ImageBiopsy Lab: First US Medical Device Approval for Austrian AI Company

VIENNA, AUSTRIA, November 20, 2019 /EINPresswire.com/ -- ImageBiopsy Lab announces that in November 2019, the first AI (Artificial Intelligence)-based algorithm for radiology applications developed by an Austrian medical AI start-up has received FDA (510K) clearance. With this approval, the medical AI software KOALA (Knee Osteoarthritis Labelling Assistant) can now be commercially offered in the leading global healthcare market USA.



KOALA objectifies the common radiological parameters of knee osteoarthritis (OA). Of this protracted and debilitating disease, 70 million patients worldwide are affected. KOALA fully automatically assesses the radiological parameters that are critical for the diagnosis of OA and thus delivers an objective reading-support within seconds. The software blends seamlessly into the existing radiological environment, benefiting both medical staff and patients.

Already approved as a medical device in Europe, the software offers clinicians a number of significant simplifications in the diagnosis of this common bone and joint disease: consistent diagnostic accuracy and objectivity enable standardized and detailed radiological follow-ups. This is particularly important for the early detection and monitoring of the disease, which often progresses for decades.

CEO Richard Ljuhar regards this not only as an award for his company, but also as a great recognition for the entire Austrian start-up scene: "We are quite happy that an Austrian start-up is one of the first European companies to receive clearance for such complex AI-based software". Ljuhar would also like to thank the long-standing supporters, investors and the entire ImageBiopsy Lab Team.

## Future market: USA

The current FDA-approved AI algorithms come mainly from industry leaders such as General Electric (GE) and Siemens Healthineers, as well as well-funded start-ups such as Zebra Medical and AiDoc (both Israel). ImageBiopsy Lab is currently ranked among the top 20 FDA approved algorithms in radiology worldwide and continues to position itself as a leader in musculoskeletal (MSK) radiology with one of the first approved AI algorithms in this discipline. With this FDA approval, the start for the market entry into the US has been made possible: the world's largest radiological conference (RSNA) will take place in early December 2019 in Chicago and is considered the official start for entry into the US. However, Ljuhar reiterates his intention to further expand our current headquarter in Vienna but to also focus on setting up a local subsidiary company in the US.

About ImageBiopsy Lab (November 2019)

ImageBiopsy Lab (IB Lab GmbH) was founded in 2016 as a spin-off of the medical technology company Braincon Technologies in Vienna. 16+ software engineers, physicians, and scientists are committed to fundamentally changing the processes, efficiency, and quality in radiology based on AI.

IB Lab is developing a novel, AI-supported modular software platform for a standardized and objective analysis of medical images. The modules of this technology platform identify/extract key radiological disease parameters that are critical for the prevention and treatment of various bone diseases. Using KOALA as an example, it is thus possible to provide a reliable support in reading knee X-ray, used by more than 50 sites worldwide every day. Additional modules for the hip and hand modules are also in use and will be submitted later this year for the FDA review. The vision to develop and certify a focused software platform for bone diseases also convinced well-known investors such as APEX Ventures and the AWS Gruenderfond, which have been on board since December 2018 as investors and fully support the further strategy of IB Lab.

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