

PRESS RELEASE

EOS imaging RECEIVES U.S. FDA 510(K) CLEARANCE FOR EOSedge™ ITS NEW GENERATION INNOVATIVE IMAGING SYSTEM

US strategic milestone: the launch of EOSedge will enlarge utilization in musculoskeletal imaging delivering best-in-class image resolution, optimized dose modulation and accelerated workflow

Paris, November 29, 2019 – EOS imaging (Euronext, FR0011191766 - EOSI - Eligible PEA - PME), a leader in 2D/3D orthopedic medical imaging and software solutions for 3D anatomical modeling and surgical planning, today announced it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its new generation imaging system, EOSedge. Receipt of FDA 510(k) clearance follows the commercial launch of EOSedge in Europe, Canada and Australia earlier this week. The new system will be unveiled at the upcoming Radiological Society of North America (RSNA) 2019 Annual Meeting starting on December 1st, in Chicago.

EOSedge is the first general X-ray system powered by a high-resolution photon counting detector, delivering optimal image quality for outstanding musculoskeletal imaging exams. EOSedge features new Flex Dose™ technology to modulate radiation dose along the patient's body, as well as an open cabin with a motorized, enlarged patient platform to facilitate easy and comfortable access for a broad range of patients to deliver larger fields of examination.

EOSedge will strengthen the portfolio of the Company, with the first-generation EOS® system continuing to be part of the EOS imaging offering. Both EOSedge and the first-generation EOS system are designed to work seamlessly with the Advanced Orthopedic Solutions, which include 3DServices, EOSapps 3D surgical planning for spine, hip and knee as well as EOSlink™, which delivers the EOS surgical plan into the operating room to be used with advanced surgical technologies.

Mike Lobinsky, Chief Executive Officer of EOS imaging, commented: “The FDA's 510(k) approval for EOSedge is a major milestone in the global marketing of this new system. After the launch in Europe, Canada and Australia, we are now ready to address the American market and offer the latest major innovation in orthopedic imaging to clinicians and patients in these key markets.”

ABOUT EOS imaging

EOS imaging is a global medical device company that designs, develops and markets innovative, low dose 2D/3D full body and weight-bearing imaging, rapid 3D modeling of EOS patient X-ray images, web-based patient-specific surgical planning, and integration of surgical plan into the operating room that collectively bridge the entire spectrum of care from imaging to post-operative assessment capabilities for orthopedic surgery. With a primary focus on hips, knees, and spine, EOS imaging is targeting a \$2 billion annual market opportunity. EOS imaging has over 350 system installations in more than 30 countries generating more than 1 million patient exams annually. EOS imaging has corporate locations in U.S., France, Canada, Germany, and Singapore, and engages more than 175 employees. For additional information, please visit www.eos-imaging.com.

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EOS imaging is listed on Compartment C of Euronext Paris
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