SyntheticMR receives FDA 510(k) clearance for their next Generation Solution SyMRI 3D

SyntheticMR announced today that their next-generation imaging solution with isotropic resolution, SyMRI 3D, has received FDA 510(k) clearance for clinical use in the United States.

SyntheticMR is proud to announce that its next-generation imaging solution, SyMRI 3D, has received FDA 510(k) clearance for clinical use in the United States. This milestone marks a significant advancement in quantitative MRI technology, offering unprecedented resolution and accuracy in brain imaging.

"We are thrilled to receive 510(k) clearance for SyMRI 3D," says Ulrik Harrysson, CEO at SyntheticMR AB. "SyMRI 3D represents the next generation of quantitative MRI, revolutionizing the landscape of medical diagnostics and offering new possibilities for diagnosis and treatment."

SyMRI 3D enables precise volumetric estimations of brain regions, a technique commonly referred to as parcellation, which empowers clinicians to gain deeper insights into brain structure and function. Furthermore, the resolution provided by SyMRI 3D facilitates comprehensive lesion analysis, ensuring a more accurate and in-depth assessment of medical conditions.

"Receiving 510(k) clearance for SyMRI 3D allows us to empower physicians to make more precise and informed decisions in diagnosis and treatment planning through quantitative imaging," says Jared Dixon, President of SyntheticMR U.S Inc.

With this clearance, SyntheticMR reaffirms its commitment to advancing medical imaging technology and providing clinicians with innovative tools to enhance patient care. SyMRI 3D opens up new possibilities for precise diagnosis, treatment planning, and monitoring, ultimately

improving patient outcomes.

This disclosure contains information that SyntheticMR AB is obliged to make public pursuant to the EU Market Abuse Regulation (EU nr 596/2014). The information was submitted for publication, through the agency of the contact person, on 27-03-2024 11:01 CET.

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SyntheticMR AB develops and markets innovative software solutions for Magnetic Resonance Imaging (MRI). SyntheticMR AB has developed SyMRI®, delivering multiple, adjustable contrast images and quantitative data from a single 5-minute scan. The SyMRI product is available in different packages. SyMRI NEURO delivers multiple contrast images, tissue segmentations and quantitative data on the brain. SyMRI MSK provides multiple contrast images and quantitative data for knee and spine anatomies. SyMRI NEURO is CE-marked, and FDA 510(k) cleared and SyMRI MSK is CE-marked. SyMRI 3D is FDA 510(k) cleared and CE-marked. SyMRI is a registered trademark in Europe and the USA. SyntheticMR is listed on the Spotlight Stock Market Exchange in Stockholm, Sweden. For more information, visit www.syntheticmr.com.