



## **FOR IMMEDIATE RELEASE**

### **Bracco Diagnostics Inc. and Subtle Medical Announce FDA Clearance of AiMIFY™ Software for Enhanced MRI**

**MONROE TOWNSHIP, N.J., OCTOBER 16, 2024** – Bracco Diagnostics Inc., a U.S. subsidiary of Bracco Imaging S.p.A, one of the world’s leading companies in the diagnostic imaging business, and Subtle Medical, Inc., a pioneering innovator in artificial intelligence (AI)-powered image acquisition, are thrilled to announce that their collaborative AI-powered software, AiMIFY™, has received FDA clearance as a Class II software as a medical device (SaMD) for magnetic resonance imaging (MRI) of the brain. This groundbreaking software, exclusively from Bracco and Subtle Medical, is designed to significantly enhance MRI of the brain, particularly for detecting small and poorly enhanced lesions.

“This FDA clearance marks a significant milestone for our innovative product, showcasing its potential to transform MRI,” said Fulvio Renoldi Bracco, Vice Chairman & Chief Executive Officer of Bracco Imaging S.p.A. “By integrating Bracco’s expertise in contrast imaging with Subtle Medical’s cutting-edge deep-learning technology, we are poised to redefine diagnostic precision and efficiency, setting new standards in the field for the ultimate benefit of the patients.”

AiMIFY™ leverages advanced AI technology to amplify the contrast enhancement of brain MR images up to two times the level obtained with a labeled dose of gadolinium-based contrast agents (GBCAs). This enhancement provides radiologists and neuroradiologists with clearer, more detailed images, improving the visibility of small and large lesions compared to standard post-contrast images. The software’s effectiveness has been validated across diverse test data, including various patient demographics, pathologies, lesion sizes, image scanner vendors, MRI sequences, and acquisition orientations.

“We partnered with Bracco to unlock the potential that AI brings to medical imaging,” said Ajit Shankaranarayanan, PhD, Chief Product Officer at Subtle Medical. “The FDA clearance represents a significant milestone for both companies, as we join forces to empower radiological professionals and improve outcomes for patients worldwide with this innovative AI-powered medical imaging solution.”

Bracco and Subtle will participate in the 110th Radiological Society of North America’s (RSNA) Scientific Assembly and Annual Meeting Dec. 1-5, 2024 in Chicago. To learn more, visit the Bracco booth #3300 and the Subtle Medical booth #4739 in the South Hall, Level 3. Additional information about RSNA Technical Exhibits can be found here: <https://www.rsna.org/news/2024/october/2024-technical-exhibits-highlights>

AiMIFY is manufactured for Bracco Diagnostics Inc. by Subtle Medical Inc. – Menlo Park, CA, USA 94025

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AiMIFY is a trademark of Bracco Imaging S.p.A.

**For additional information about Bracco's products, and for full prescribing information, please visit <http://imaging.bracco.com/us-en>.**

**About Bracco Imaging**

Bracco Imaging S.p.A. ("Bracco Imaging"), part of the Bracco Group, is an innovative world leader delivering end-to-end products and solutions through its comprehensive portfolio across diagnostic imaging modalities. Headquartered in Milan, Italy, Bracco Imaging's purpose is to improve people's lives by shaping the future of prevention and precision diagnostic imaging. The Bracco Imaging portfolio includes products and solutions for all key diagnostic imaging modalities: X-ray imaging, magnetic resonance imaging (MRI), Contrast Enhanced Ultrasound (CEUS), and Nuclear Medicine through radioactive tracers and novel PET imaging agents. Bracco Imaging has 3,800 employees and operates in more than 100 markets globally. Bracco Imaging has a well-skilled and innovative Research and Development (R&D) organization with an efficient process-oriented approach and track record in the diagnostic imaging industry. Discover Bracco at [www.bracco.com](http://www.bracco.com)

**About Subtle Medical**

Subtle Medical is a global leader in AI-powered technology for faster, safer, and smarter medical imaging. The company's cutting-edge solutions for faster imaging optimize radiology workflows, improving productivity and patient experience. Subtle Medical has been recognized as a CB Insights GenAI 50 company and has been named to the CB Insights Top AI 100 and Digital Health 150 lists multiple times. By harnessing the power of artificial intelligence, Subtle Medical is transforming the future of healthcare. For more information, please visit [subtlemedical.com](http://subtlemedical.com) or email [sales@subtlemedical.com](mailto:sales@subtlemedical.com).

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