

Bracco Marks Major Global Milestone with U.S. FDA 510(k) Clearance and Health Canada Authorization for VueJect®, the First Dedicated Ultrasound Contrast Delivery System to Support Cardiology Imaging

VueJect® strengthens Bracco's integrated CEUS ecosystem by enabling more standardized, efficient contrast administration in cardiology imaging

MILAN, August 11, 2026 -- Bracco Imaging today announced that VueJect®, its first dedicated ultrasound contrast delivery system engineered to specifically support cardiology imaging, has received 501(k) clearance from the U.S. Food and Drug Administration (FDA) and authorization from Health Canada. These regulatory milestones represent the first step in Bracco's broader global commercialization strategy for VueJect, reinforcing the company's long-term commitment to advancing contrast-enhanced ultrasound (CEUS). VueJect will initially be available in the United States and Canada, with additional regulatory submissions planned in other markets.

VueJect expands Bracco's growing CEUS ecosystem by providing a dedicated contrast delivery solution designed to:

- **Improve workflow efficiency** through a streamlined contrast administration process
- **Reduce operator variability** leading to consistency during contrast administration
- **Enable continuous administration** of ultrasound contrast agents to support more consistent enhancement during cardiac imaging procedures.

*"VueJect represents a significant strategic milestone for Bracco as we continue investing in innovations that advance contrast-enhanced ultrasound worldwide," said **Fulvio Renoldi Bracco**, Vice Chairman and CEO, Bracco Imaging. "Beginning with regulatory approvals in the United States and Canada, VueJect further advances our integrated ultrasound portfolio and reflects our commitment to expanding access to innovative diagnostic solutions around the world."*

*"VueJect is a defining addition to our CEUS ecosystem, adding a dedicated injector to our Ultrasound-Enhancing Agent portfolio that is able to administer Lumason/SonoVue in dilution in Echocardiography procedures," said **Luca Frazzoli**, Global Head of Ultrasound, Bracco Imaging. "As we bring this technology to more markets, we expect it to change what sonographers and physicians come to expect from contrast administration, setting a new standard for consistency and confidence in everyday practice."*

*"FDA clearance and Health Canada authorization mark an important milestone for clinicians across North America," said **Robert Mitchell**, MBA, Director, Ultrasound Platform Americas. "VueJect provides cardiac sonographers with a more standardized approach to contrast administration, helping deliver more consistent CEUS examinations, day in and day out."*

Following these regulatory milestones in the United States and Canada, Bracco is preparing for commercial launch while advancing plans for future regulatory submissions in additional global markets. VueJect marks the latest step in Bracco's investment in contrast-enhanced ultrasound.

VueJect has received 510(k) clearance from the U.S. Food and Drug Administration and is licensed by Health Canada under Medical Device License No. 115637. For complete operating instructions, warnings, precautions, and other important safety information, refer to the instructions for use.



About Bracco

Bracco Group, founded in 1927, is a global leader in diagnostic imaging, committed to advancing healthcare and improving people's lives by shaping the future of prevention and precision medicine.

The company operates in the healthcare sector across more than 100 countries with a workforce of over 4,000 employees and consolidated annual revenues of approximately €2 billion, 88% generated by international markets.

With a strong commitment to innovation - investing around 9% of its reference turnover in Research & Development - Bracco develops and provides a broad portfolio of pharmaceutical products for diagnostic imaging, including contrast agents for X-ray, Computed Tomography (CT), and Magnetic Resonance Imaging (MRI), as well as microbubbles for Contrast Enhanced Ultrasound (CEUS), and Molecular Imaging through radioactive tracers and novel PET imaging agents, alongside AI-based solutions. It is also a global market leader in advanced contrast management technologies for cardiovascular angiography and radiology imaging.

Discover more at www.bracco.com.

VUEJECT is a registered trademark of Bracco Imaging S.p.A.

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