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Company announcement

PME receives FDA clearance for Visage 7 | AI - Mammography

25 November 2026

HIGHLIGHTS

- **PME receives FDA 510(k) clearance for Visage 7 | AI - Mammography.**
- **Visage 7 | AI – Mammography is an AI reading aid for screening mammography (2D and 3D tomosynthesis), integrated into Visage 7.**
- **FDA clearance was supported by a multi-reader multi-case (MRMC) clinical study in which radiologists performed better when reading with the medical device.**
- **Includes a Predetermined Change Control Plan (PCCP), an FDA-reviewed pathway for defined future updates, including support for additional mammography systems.**

Leading health imaging company Pro Medicus Limited [ASX: PME] today announced its wholly-owned U.S. subsidiary, Visage Imaging, Inc., has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for Visage 7 | AI – Mammography**.**

Visage 7 | AI – Mammography is an artificial intelligence (AI) software application intended as a concurrent reading aid for radiologists interpreting full-field digital mammography (FFDM) and digital breast tomosynthesis (DBT) examinations. It highlights calcification groups and soft-tissue regions suspicious for breast cancer and assigns lesion-level and breast-level scores that reflect the likelihood that cancer is present. Results are displayed within the Visage 7 diagnostic viewer, on the Visage 7 Enterprise Imaging Platform (“Visage 7”), in the radiologist's existing reading workflow.

FDA clearance is supported by a multi-reader multi-case (MRMC) clinical study, in which radiologists performed better when reading with Visage 7 | AI – Mammography than without it, and by a standalone performance evaluation on a large cohort of U.S. screening examinations.

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FDA clearance includes a Predetermined Change Control Plan, which defines future modifications, including support for additional mammography systems, that may be implemented under the cleared plan without a new 510(k) submission. The device is initially cleared for use with Hologic Selenia Dimensions systems.

Visage 7 | AI – Mammography is now available for Visage 7 customers in the U.S.

Dr Sam Hupert, Pro Medicus CEO, said "Breast cancer screening is where AI can make one of its biggest differences, and that is exactly what we built Visage 7 | AI - Mammography for."

Dr Hupert continued, "Our goal is to help radiologists find more cancers early, and to spare more women the anxiety of an unnecessary call-back or biopsy. It runs natively inside Visage 7, so that help is right there in the viewer radiologists already use. And with our Predetermined Change Control Plan cleared alongside it, we have an FDA-reviewed path to keep making it better."

Authorised by the Board of Pro Medicus Limited.

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About Pro Medicus Limited:

Pro Medicus Limited [ASX: PME] is a leading healthcare informatics company. Founded in 1983, the company provides a full range of medical imaging software and services to hospitals, imaging centres and health care groups worldwide. In January 2009, the company acquired Visage Imaging transforming it into a global provider of leading-edge medical imaging solutions. The company's Visage 7 suite of products are the foundation of an ultra-fast, clinically rich, and highly scalable platform that is seamlessly deployable in both public or private cloud environments. The company offers a leading suite of RIS, PACS, Artificial Intelligence and e-health solutions constituting one of the most comprehensive end-to-end offerings in healthcare imaging. Pro Medicus has offices in Melbourne, Berlin and San Diego. www.promedicus.com.au

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