PERIMETER

Perimeter Medical Imaging AI's 'Claire' Becomes First FDA-approved AI-Enabled Imaging Device for Breast Cancer Surgery

Claire demonstrated a statistically significant reduction in patients with residual cancer post-surgery compared to the standard of care alone

Social Capital's Chamath Palihapitiya highlights Claire as a compelling example of how AI innovation can drive meaningful medical impact

Company plans nationwide launch of real-time AI tool for margin assessment designed to help surgeons reduce repeat surgeries

TORONTO and DALLAS, March 3, 2026 /CNW/ - Perimeter Medical Imaging AI, Inc. (TSXV: PINK) (OTCQX: PYNKF) ("Perimeter" or the "Company"), a commercial-stage medical technology company, announced today that it has received U.S. Food and Drug Administration ("FDA") premarket approval ("PMA") for Claire™ (formerly the Perimeter OCT B-Series with ImgAssist AI 2.0), the first AI-enabled imaging device approved in the United States for intraoperative breast cancer margin assessment. The technology received Breakthrough Device designation from the FDA and is designed to enhance surgeons' ability to detect difficult-to-see cancer during breast-conserving surgery and potentially reduce the need for re-operations.

"Repeat breast cancer surgeries due to residual disease remain a significant clinical, health, and economic burden," said Perimeter CEO, Adrian Mendes. "Claire's FDA approval marks a major milestone in breast cancer care, as we advance our goal of reducing repeat surgeries so that no patient has to be told 'we didn't get it all.' We plan to begin a nationwide launch in the coming weeks so that surgeons can rapidly adopt the industry's first FDA-approved real-time AI-powered imaging technology for breast cancer surgery."

Innovating the Standard of Care

Claire combines Perimeter's proprietary AI with its patented wide-field OCT imaging to enable high-resolution, real-time evaluation of excised tumor margins. The system delivers 10 times higher resolution than standard X-ray and ultrasound at 2mm imaging depth - the clinically relevant margin width for breast cancer margin assessment. Claire's innovative AI technology was trained on Perimeter's proprietary and growing OCT image library of over 2 million breast tissue images.

Today, surgeons use a combination of physical examination, and in limited cases intraoperative pathology to assess margins before sending specimens to pathology for final evaluation. As a result, patients may wait up to a week or more to learn whether margins are clear or additional surgery is required. Claire is designed to identify areas of concern during surgery, helping surgeons determine whether to remove more tissue before completing the procedure. Today, national averages indicate repeat surgeries occur in about 20 percent of breast-conserving surgeries in the United States.[1]

"Despite progress in breast cancer treatment, intra-operative margin assessment remains challenging, often leading to excess removal of healthy tissue, re-operations, and anxiety for patients as they await pathology results," said Dr. Alastair Thompson, Surgeon and Professor, Section Chief of Breast Surgery, Olga Keith Wiess Chair of Surgery at Baylor College of Medicine, Breast Cancer Program Leader at the Dan L Duncan Comprehensive Cancer Center, and the Primary Principal Investigator of the pivotal trial that supported Claire's PMA application. "Claire has the potential to become a new standard in breast surgical care helping reduce re-excisions while improving patient outcomes."

Claire's Trial Demonstrated Statistically Significant Improvement

The pivotal trial of Claire demonstrated an 88.1% margin accuracy and a statistically significant reduction in patients with residual cancer post-surgery compared to the standard of care alone. As presented by Dr. Thompson at the 26th Annual Meeting of the American Society of Breast Surgeons (ASBrS 2025), these results demonstrated super-superiority (lower bound of confidence interval for treatment effect greater than a predetermined minimal clinically meaningful difference) of its ability to aid surgeons in achieving clear surgical margins. This large-scale pivotal clinical trial would not have been possible without the generous grant of US$7.4 million from the Cancer Prevention and Research Institute of Texas (CPRIT).

A critical innovation behind Claire is its AI engine, trained on millions of proprietary OCT images of cancerous and healthy tissue. This image library can only be generated using Perimeter's patented OCT imaging engine and represents a unique advantage, as every surgical procedure performed with Claire generates new data that can be used to improve the AI product, helping to create better outcomes for future patients. Claire has been designed and developed on a diverse data set spanning a multitude of patient characteristics to help surgeons assess areas of interest during surgery. This use of AI is what makes Claire one of the few AI-enabled class III devices on the U.S. market today. A pre-determined change control plan (PCCP) was authorized as part of the PMA approval and includes planned AI enhancements that can be implemented without additional FDA interaction.

"Developing AI for clinical use is incredibly challenging, requiring large, high-quality datasets that reflect real-life patient diversity," said Perimeter's Chief Innovation Officer and co-founder, Andrew Berkeley. "This approval reflects years of hard work with our clinical partners integrating AI directly into surgical decision-making and advancing its role from operational support to real-time patient care."

Platform Opportunity

Claire's FDA approval positions Perimeter at the forefront of AI-enabled intraoperative imaging and marks the first commercialization of its proprietary OCT-AI platform. The Company's patented wide-field OCT technology, proprietary dataset, and integrated AI capabilities target an estimated 300,000 annual U.S. breast cancer surgeries, while providing a scalable foundation for expansion into additional cancer indications over time.[2]

Management believes this innovative, patented platform represents the initial step toward addressing a significantly larger global opportunity across additional cancer surgeries, biopsy procedures, and pathology applications.

Renowned Silicon Valley venture capitalist, entrepreneur, and former Facebook executive, Chamath Palihapitiya, commented, "I've been a major investor in Perimeter for several years, and it's been the incredible clinical and commercial potential of Claire that has driven my excitement all along. After rigorous development, clinical and regulatory engagement, and collaboration with the medical community, I believe Perimeter is at the starting line of something truly transformational."

Palihapitiya continued, "Claire delivers greater peace of mind. Both for the surgeon who currently faces nearly 1-in-5 odds of needing to perform repeat surgery due to positive margins, and for the breast cancer patient, who, under the current paradigm, typically has to wait (and worry) for up to 10 days to learn whether an additional surgery is required. A second surgery is an emotional and physical journey that we are trying to prevent. This is exactly the kind of AI-driven innovation that can improve the standard of care by delivering measurable, real-world medical impacts. I'm excited to see what Perimeter can accomplish, as it commercializes the first AI-enabled imaging device for breast cancer surgery."

Sources

[1] Kim Y, Ganduglia-Cazaban C, Tamirisa N, et al. Contemporary Analysis of Reexcision and Conversion to Mastectomy Rates and Associated Healthcare Costs for Women Undergoing Breast-Conserving Surgery. Ann Surg Oncol. 2024;31:3649-3660

[2] American Cancer Society, Breast Cancer Facts & Figures, 2024-2025.

About Perimeter Medical Imaging AI, Inc.

Based in Toronto, Canada and Dallas, Texas, Perimeter Medical Imaging AI (TSX-V: PINK) (OTCQX: PYNKF) is a medical technology company driven to transform cancer surgery with ultra-high-resolution, real-time, advanced imaging tools to address areas of high unmet medical need. Claire, recently approved by the FDA, is our next-generation AI-enabled device. The Company's ticker symbol "PINK" is a reference to the pink ribbons used during Breast Cancer Awareness Month.

Indications for Use: The Claire OCT System is an adjunctive three-dimensional imaging tool which provides volumetric cross-sectional, real-time depth visualization, coupled with an artificial intelligence computer-aided detection algorithm which identifies and marks focal areas suspicious for breast cancer. It is used concurrently with physician interpretation of the images. The Claire OCT System is intended for use in conjunction with other standard methods for evaluation of the margins of excised lumpectomy tissue during surgical procedures in patients with a biopsy-confirmed diagnosis of breast cancer.

The Claire OCT System should not be used to replace standard tissue histopathology assessment and should not be used for diagnosis. The device is not intended for use in any of the following individuals: under the age of 18, male, have metastatic cancer (Stage IV), have lobular carcinoma as their primary diagnosis, have had previous ipsilateral breast surgery for benign or malignant disease within two years (including implants and breast augmentation), patients with multi-centric disease (histologically diagnosed cancer in two different quadrants of the breast), unless resected in a single specimen, patients with bilateral disease (diagnosed cancer in both breasts), patients who are currently lactating, patients who are currently pregnant, or concurrent use in surgeries with cryo-assisted localization. Refer to prescriber labeling for full safety information.

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Forward-Looking Statements

This news release contains statements that constitute "forward-looking information" within the meaning of applicable Canadian securities legislation. In this news release, words such as "may," "would," "could," "will," "likely," "believe," "expect," "anticipate," "intend," "plan," "estimate," and similar words and the negative form thereof are used to identify forward-looking statements. Forward-looking information may relate to management's future outlook and anticipated events or results and may include statements or information regarding the future financial position, business strategy and strategic goals, competitive conditions, research and development activities, projected costs and capital expenditures, research and clinical testing outcomes, taxes and plans and objectives of, or involving, Perimeter. Without limitation, information regarding the potential benefits and the commercialization of Claire and potential future market size and opportunity are forward-looking information. Forward-looking statements should not be read as guarantees of future performance or results, and will not necessarily be accurate indications of whether, or the times at or by which, any particular result will be achieved. No assurance can be given that any events anticipated by the forward-looking information will transpire or occur. Forward-looking information is based on information available at the time and/or management's good-faith belief with respect to future events and are subject to known or unknown risks, uncertainties, assumptions, and other unpredictable factors, many of which are beyond Perimeter's control. Such forward-looking statements reflect Perimeter's current view with respect to future events, but are inherently subject to significant medical, scientific, business, economic, competitive, political, and social uncertainties and contingencies. In making forward-looking statements, Perimeter may make various material assumptions, including but not limited to (i) the accuracy of Perimeter's financial projections; (ii) obtaining positive results from trials; (iii) obtaining necessary regulatory approvals; and (iv) general business, market, and economic conditions. Further risks, uncertainties and assumptions include, but are not limited to, those applicable to Perimeter and described in Perimeter's Management Discussion and Analysis for the year ended December 31, 2024, which is available on Perimeter's SEDAR+ profile at https://www.sedarplus.ca, and could cause actual events or results to differ materially from those projected in any forward-looking statements. Perimeter does not intend, nor does Perimeter undertake any obligation, to update or revise any forward-looking information contained in this news release to reflect subsequent information, events, or circumstances or otherwise, except if required by applicable laws.

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Perimeter’s Claire™ uses optical coherence tomography and AI to help surgeons detect difficult-to-see cancer during breast conserving surgery (CNW Group/Perimeter Medical Imaging AI Inc.)

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