

CardioRenal Systems Secures FDA IDE Approval and Strategic Hospital Investment

FDA approves Investigational Device Exemption (IDE) for pivotal study and investment from St. Elizabeth Healthcare advances RenalPro™ toward the U.S. market.

MILFORD, MA, UNITED STATES, July 7, 2026 /EINPresswire.com/ -- [CardioRenal Systems](#), a clinical-stage medical device company developing RenalPro™, a first-of-its-kind device intended to prevent Acute Kidney Injury (AKI) in hospitalized patients, today announced two significant milestones: receipt of FDA Investigational Device Exemption (IDE) approval for the pivotal trial of RenalPro™ in Cardiac Surgery, and new investments from [St. Elizabeth Healthcare](#) and Angel Physicians Fund.

The IDE approval authorizes CardioRenal Systems to begin enrollment in a pivotal trial of RenalPro™ for the prevention of Cardiac Surgery-Associated Acute Kidney Injury (CSA-AKI), representing an important regulatory milestone on the path to U.S. market approval. This follows CardioRenal's earlier FDA Breakthrough Device Designation and builds upon European clinical evidence, including multiple randomized, controlled trials that supported the device's CE Mark.

"IDE approval is a significant milestone for CardioRenal and for the many patients who undergo cardiac surgery each year and remain at serious risk of acute kidney injury," said Ilya Budik, Chief Executive Officer of CardioRenal Systems.

The company recently secured investment from St. Elizabeth Healthcare, a regional health system serving patients in Northern Kentucky, Southeastern Indiana and Greater Cincinnati. St. Elizabeth's cardiac surgery program, based at the Florence Wormald Heart and Vascular Institute in Edgewood, Ky., is ranked among the top 10% of programs nationwide by the Society of Thoracic Surgeons. Lori Ritchey-Baldwin, Executive Vice President and Chief Financial Officer at St. Elizabeth said, "Acute kidney injury has a real impact—not just on hospital resources, but on



RenalPro™ Device

patient outcomes and recovery. Innovations like RenalPro™ represent an important step toward improving both."

"We are excited to back CardioRenal Systems and its leadership team," said Dr. Manish Bhandari, a physician at St. Elizabeth Healthcare and founder and managing partner of the Angel Physicians Fund, a venture capital firm focusing on life sciences and healthcare. "This investment is part of our commitment to clinical innovation and serving as a regional leader in cardiovascular care and advanced surgical technology. The results from the KIDNEY Study underscore the potential of RenalPro™ to become a new standard-of-care for AKI prevention."

Together, the IDE approval and the new investments mark an important inflection point for CardioRenal Systems. The company is now working towards beginning its pivotal study in centers across the US and Europe.



CardioRenal Executive Team (Left to Right): Dr. Heyman Luckraz - SVP Medical Affairs, Shmulik Adler - SVP Clinical & Regulatory Affairs, and Ilya Budik - CEO



CardioRenal Systems™

CardioRenal Systems Logo

ABOUT ACUTE KIDNEY INJURY (AKI)

AKI affects millions of hospitalized patients each year and is associated with approximately 286,000 deaths annually in the United States alone¹. Since 2025, the Centers for Medicare & Medicaid Services (CMS) have classified AKI as a "Hospital Harm" quality-reporting metric. In cardiac surgery, more than 30% of patients develop AKI following otherwise successful procedures,² extending ICU stays by two to six days³ and substantially increasing cost and mortality.⁴ By preventing AKI, RenalPro™ can improve hospital margins and free critical ICU capacity — aligning clinical benefit with clear economic value in a multibillion-dollar addressable market.

ABOUT CARDIORENAL SYSTEMS

CardioRenal Systems is a medical device company dedicated to protecting kidney function during medical procedures and reducing the incidence of Acute Kidney Injury. Its first mission is to prevent Cardiac Surgery-Associated Acute Kidney Injury (CSA-AKI) and improve outcomes for patients undergoing cardiac interventions worldwide. In multiple randomized, controlled European studies, the technology has demonstrated strong safety and efficacy and has been granted the CE Mark, positioning RenalPro™ as the first clinically validated solution dedicated to the prevention of AKI. Headquartered in Milford, Massachusetts, CardioRenal Systems is a



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*Lori Ritchey-Baldwin, EVP &
CFO of St. Elizabeth
Healthcare*

privately held medical device company. To learn more, visit www.cardiorenalsystems.com.

ABOUT ST. ELIZABETH HEALTHCARE

St. Elizabeth Healthcare operates six facilities and more than 172 primary care and specialty practices throughout the Northern Kentucky, Southeastern Indiana and Greater Cincinnati region. Sponsored by the Diocese of Covington, St. Elizabeth is a mission-based organization committed to improving the health of the communities it serves, providing more than \$100 million in uncompensated care and benefits to the community each year. St. Elizabeth is a leader in the Greater Cincinnati region by providing quality care, as demonstrated by the following accolades: St.

Elizabeth Edgewood was named the top hospital in Kentucky by U.S. News in 2025, multiple hospitals achieving 5-star ratings from the Centers for Medicare and Medicaid Services, multiple hospitals earning Magnet Recognition® for nursing excellence and its physicians group receiving the American Medical Group Association’s Acclaim Award for excellence and innovation. To learn more, visit www.StElizabeth.com

REFERENCES

- 1 Brown, J. et al. Hospital Mortality in the United States following Acute Kidney Injury, BioMed Research International, 2016.
- 2 Warren, J. et al. Incidence and impact of acute kidney injury in patients with acute coronary syndromes treated with coronary artery bypass grafting. American Heart Journal, Jan. 2016.
- 3 Hu, J. et al. Global Incidence and Outcomes of CSA-AKI: A Meta-Analysis of 320,000 Patients. Journal of Cardiothoracic and Vascular Anesthesia, 2016.
- 4 Alshaikh, H. et al. Financial Impact of CSA-AKI. Annals of Thoracic Surgery, 2018.

FORWARD-LOOKING STATEMENTS

This release contains forward-looking statements regarding CardioRenal Systems’ clinical development plans, financing, and the potential of RenalPro™. Such statements are subject to risks and uncertainties, including the outcome of clinical trials and FDA review. In the United States, RenalPro™ is investigational and has not been demonstrated to be safe or effective. There is no assurance it will receive marketing authorization or become commercially available. Actual results may differ materially from those expressed or implied. Outside of the US, the device holds a CE mark for balanced fluid management under the name RenalGuard Therapy®.

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