Amarex Client Receives U.S. FDA Marketing Approval for Hemoconcentrators

Amarex leveraged knowledge gleaned from past FDA applications to finish 510(k) studies and application in five months, leading to rapid clearance.

Amarex Clinical Research

GERMANTOWN, MD, UNITED STATES, March 11, 2024 /EINPresswire.com/ -- Amarex Clinical Research, LLC, an NSF company is pleased to announce its client Tecnoideal America, Inc. received U.S. FDA 510(k) clearance for hemoconcentrators used in adult patients during or after cardiopulmonary bypass surgery to remove excess fluids from the blood and restore physiological blood conditions. This product successfully completed performance and substantial equivalence testing, and the data proved the device to be substantially equivalent to the predicate device.

> This demonstrates Amarex's capacity for successful collaboration and highlights our strength in product development."
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> *Dr. Ahmad Bayat, Head, Global Regulatory and Clinical Affairs*

Amarex's regulatory department worked together with Tecnoideal America to design the necessary performance and substantial equivalence tests. Amarex's regulatory department prepared the 510(k) application. Dr. Ahmad Bayat, Head, Global Regulatory and Clinical Affairs stated that, "We worked closely with Tecnoideal to initiate this development by leveraging knowledge learned from past FDA applications and by adhering to current FDA recommendations. As a result, the 510(k) studies and application were finished within five months, leading to rapid 510(k) clearance. This accomplishment demonstrates Amarex's capacity for successful collaboration and highlights our strength in product development."

President of Medica S.p.A., Tecnoideal's parent company, Luciano Fecondini commented, "We are excited to achieve U.S. FDA approval for our hemoconcentrators. This milestone marks the first approval of blood purification devices, and we have already begun the 510(k) application process for other devices in our pipeline."

About Amarex Clinical Research, LLC, an NSF company
Amarex Clinical Research, LLC, an NSF company, is a global, full-service Contract Research Organization (CRO), whose leadership team has significant expertise conducting biomedical research. Their combined experience includes the design and conduct of several hundred clinical research projects in many therapeutic indications.


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Amarex provides services in Project Management: Phase I-IV, BE/BA, PK/PD; Regulatory Affairs: FDA Applications and meetings, applications to International Health Authorities, GxP Compliance Audits; Clinical Operations; Adaptive Study Designs; Statistical Analysis; Data Management; Medical Monitoring; Safety and Pharmacovigilance; and General Consulting. Amarex can take your product through the entire approval process, from creating the regulatory approval strategy, to conducting trials, to writing the marketing approval application. Join our growing list of clients with approved products assisted by quality, cost-efficient services. For more information visit www.amarexcro.com.

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