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BioE RECEIVES FDA 510(K) CLEARANCE FOR CORD BLOOD PROCESSING SYSTEM

PrepaCyte-CB available immediately to public and private cord blood banks seeking simple and cost-effective method to separate potentially therapeutic cells and stem cells from cord blood

PrepaCyte-CB only cord blood processing system of its kind cleared by FDA; milestone adds to Minnesota's long history of cord blood leadership

ST. PAUL, Minn. — Jan. 14, 2009 — [BioE[®], Inc.](#), a biomedical company that provides enabling cord blood stem cell tools and technologies, announced today it received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for its [PrepaCyte[®]-CB Processing System](#) for umbilical cord blood.

PrepaCyte-CB provides public and private cord blood banks a simple and cost-effective method for processing umbilical cord blood to obtain potentially therapeutic cells — total nucleated cells (TNCs) and CD34+ hematopoietic stem/progenitor cells — for eventual transplantation in humans. Available immediately, PrepaCyte-CB is the only cord blood processing system of its kind cleared by the FDA.

“We are excited about PrepaCyte-CB’s ability to improve the quality and bankability of cord blood units during a time of rapid growth for cord blood utilization in transplantation,” said Gayl Chrysler, vice president of cellular therapies and clinical affairs for BioE.

“The benefits of PrepaCyte-CB were so readily apparent during BioE’s clinical study that it was an easy decision to switch to this new processing platform,” said [Donald Hudspeth, BSCLS, MT\(ASCP\)](#), general manager and international projects manager for [Cryobanks International](#), a public and private cord blood bank in Alamonte Springs, Fla. and BioE clinical study participant. “PrepaCyte-CB enables us to process cord blood units safely and reliably, control costs, and consistently obtain quality cord blood units with greater transplantation potential due to increased TNC and CD34+ stem cell recoveries.”

PrepaCyte-CB Quality

- PrepaCyte-CB recovers high yields of TNCs, mononucleated cells (MNCs) and CD34+ hematopoietic stem/progenitor cells from human umbilical cord blood, according to the results of BioE’s multi-site, in-vitro clinical study.

- PrepaCyte-CB consistently removes approximately 99 percent of red blood cells (RBCs) from the final processed cord blood unit, according to BioE's clinical study. This benefit maximizes available cryopreservation space and reduces potential ABO incompatibility issues.
- PrepaCyte-CB leaves desired TNCs and stem cells unmodified and unaffected during cord blood processing.

PrepaCyte-CB Simplicity & Cost Effectiveness

- PrepaCyte-CB is intuitive and easy-to-use, permitting quick implementation within new and existing cord blood banks.
- PrepaCyte-CB allows batch processing and reduces "hands on" staff time. Cryobanks realized a time-savings of 50 minutes per cord blood unit using PrepaCyte-CB compared to its previous hetastarch processing method.
- PrepaCyte-CB requires no costly capital equipment or maintenance fees. Only a standard laboratory centrifuge is required to concentrate desired cells after separation.
- PrepaCyte-CB integrates with [STEMSOFT Software Inc.'s StemLab](#) to efficiently record, track and manage all associated cell processing and storage data.

Other PrepaCyte-CB Product Features

- PrepaCyte-CB is a sterile device composed of three integrally attached processing and storage bags containing the PrepaCyte-CB separation solution. The system's interconnected, closed-bag set limits cell manipulation and helps minimize environmental contamination and identification errors.
- PrepaCyte-CB's bag set and separation solution are sterile and shown to be non-toxic.
- PrepaCyte-CB is manufactured under FDA current Good Manufacturing Practices (cGMP).

BioE holds numerous U.S. and worldwide patents for the cell separation methods and compositions used in the PrepaCyte-CB System; other related patents are pending. For additional information, clinical study data and a visual representation of how the PrepaCyte-CB System works, visit www.bioe.com/prepacytecb.

About BioE

Headquartered in St. Paul, Minn., BioE is a biomedical company that provides enabling cord blood stem cell tools and technologies. The company's proprietary PrepaCyte®-CB Processing System easily and efficiently separates stem cells from cord blood for cryopreservation and eventual transplantation in humans. BioE's clonal, cord blood-derived [Multi-Lineage Progenitor Cell™ \(MLPC™\) stem cell](#) — isolated using the company's PrepaCyte cell separation platform — can differentiate into multiple cell types and lineages and is readily available to clinicians and researchers for therapeutic research and drug discovery. BioE is privately owned and was founded in 1993. For more information about the company, please visit www.bioe.com or call (800) 350-6466.

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