Today Biom'Up announced it has received FDA clearance for the HEMOBLAST™ Bellows IDE pivotal clinical trial design.

The prospective, randomized, controlled, multi-center clinical investigation evaluates the safety and efficacy of HEMOBLAST™ Bellows, the company’s novel hemostat, in cardiothoracic, abdominal, and orthopedic lower extremity surgeries.

The study meets the FDA requirement for reliability by establishing the eligibility of the target bleeding site and achievement of hemostasis based on the SPOT GRADE™, a validated Surface Bleeding Severity Scale (SBSS), that is a proprietary creation of Biom'Up.

Hemorrhage is associated with approximately 37% of deaths after trauma, including mortality in the field as well as in hospital setting. Furthermore, the vast majority of preventable trauma-related deaths are caused by hemorrhage.*

The total US market for hemostats is estimated at 900 million USD.**

HEMOBLAST™ Bellows (Hemoblast) is an investigational device, not currently for sale in the US that is intended for use in surgical procedures as an adjunct to hemostasis when control of bleeding by conventional procedures is ineffective or impractical.

Since its formation in 2005, Biom'Up has been developing medical devices based on patent protected biopolymers. Using this experience, Biom'Up has created innovative and clinically proven products that cover many different surgical specialties – orthopedics, spinal, cardiac, general, and maxillo-facial and dental. Biom'Up is committed to the design and development of novel high-performing solutions that make life easier for surgeons and better for patients.


** DNA-Ink Research.

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