FDA approves raplixa to help control surgical bleeding

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(HealthDay)—Raplixa (human fibrin sealant) has been approved by the U.S. Food and Drug Administration to help control bleeding during surgery, the agency said in a news release.

Raplixa's use is sanctioned when standard surgical techniques—such as suture, ligature, or cautery—are "ineffective or impractical," the FDA said. The spray-dried fibrin sealant is dissolved in the blood and triggers a reaction that promotes clotting. The product contains fibrinogen and thrombin derived from human plasma. Its manufacturing process includes purification designed to render blood-borne viruses inactive, the agency said.

Raplixa, designed to be used with an absorbable gelatin sponge, was clinically evaluated among more than 700 people over 11 months. The most common side effects included surgical pain, nausea, constipation, fever, and hypotension.

"The spray-drying process used to manufacture Raplixa produces dried powders that can be combined into a single vial," Karen Midthun, M.D., director of the FDA's Center for Biologics Evaluation and Research, said in a statement. "This eliminates the need to combine the fibrinogen and thrombin before use and allows the product to be stored at room temperature."

The product is manufactured by ProFibrix BV, a unit of The Medicines Company, based in Parsippany, N.J.

More information: More Information