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FDA OKs heart valve made from human tissue

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The U.S. Food and Drug Administration has approved the first replacement heart valve made from donated human tissue in which the cells have been removed.

Traditionally, when human tissue is recovered from a cadaver for future implantation, it is inspected, cleaned and decontaminated to prevent infection, but the allograft (human) product remains otherwise unchanged.

The FDA said CryoLife Inc. has added a manufacturing step to its CryoValve SynerGraft Pulmonary Valve and Valved-Conduit Allograft that removes the tissue's cells and cellular debris.

What remains is a scaffold of connective tissue that still functions like a human heart valve, potentially lowering the risk of an immune response and subsequent tissue rejection, the FDA said.

Allograft heart valves are popular choices for children because they avoid the need to take blood-thinning medications on a long-term basis, officials said, and are less likely to calcify than are heart valves from a pig or cow.

The FDA said the SynerGraft valve is for use in patients who require replacement of their pulmonary valve because of disease, malformation or malfunction of their own pulmonary valve, or as part of another surgical procedure.

CryoLife is based in Kennesaw, Ga.