DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS DESCRIBED IN 21 CFR 1271.10

FEI: 3012131184

Other FDA Registrations:
Blood:
Devices: FEI: 3012131184
Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025
Last Registration Receipt Date: 11/21/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

Curiteva, INC
25127 Will McComb Drive

Alabama
Tanner, Alabama 35671
USA

Phone: 256-213-1057 **Ext.:**

Reporting Official:

Amy Swenson, Director Regulatory Compliance
25127 Will McComb Drive
Tanner, Alabama 35671
USA
Phone: 256-213-1057 Ext. 114
aswenson@curiteva.com

Satellite Recovery Establishment: No
Parent Manufacturing Establishment FEI No.:
Testing For Micro-Organisms Only: No

Note: FDA acceptance of an establishment registration and HCT/P listing does not constitute a determination that an establishment is in compliance with applicable rules and regulations or that the HCT/P is licensed or approved by FDA (21 CFR 1271.27(b)).

HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane							X		X			CuriGraft Amniontic Membrane
Blood Vessel												
Bone							X		X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage												
Cornea												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue							X		X			CuriGraft Max Amnion Patch

FDA information collection OMB Control number: 0910-0543, expiration date: 08/31/2026

Additional Information: Added umbilical cord and changed Curigraft Max Amnion Patch from Amniotic Membrane to umbilical cord

Proprietary Name(s):	Bone	CuriGraft Osteoinductive Carrier Matrix, CuriGraft DBM Putty, CuriGraft Cancellous Sponge, CuriGraft Viable Allogenic Bone Matrix, H-Genin DBM Putty, Lordotic Cortical Cervical Spacer, LG Lordotic Cortical Cervical Spacer, Assembled Cervical Lordotic (Saline), CuriGraft Demineralized Bone Fibers

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