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

Ext.:

FEI: 3003413152

Other FDA Registrations: Blood: Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/10/2024 Summary Report Print Date: 12/20/2024

No

Legal Name and Location:

AlloSource

9 Worthington Access Dr.

Maryland Heights, Missouri 63043

USA

Phone: 314-781-0246

Reporting Official:

Trevor Wright, Director of Regulatory Affairs

6278 South Troy Circle Centennial, Colorado 80111

USA

Phone: 720-873-0213 Ext. twright@allosource.org

Satellite Recovery Establishment:

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)).

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

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3003413152 Legal Name: AlloSource