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: 3000215346

Other FDA Registrations:
Blood:
Devices: FEI: 3000215346
Drugs:

Reason For Last Submission: Change in Information
Last Annual Registration Year: 2020
Last Registration Receipt Date: 07/17/2020
Summary Report Print Date: 07/21/2020

Legal Name and Location:

AlloSource
6278 South Troy Circle

Centennial, Colorado 80111
USA

Phone: 720-873-0213 **Ext.:**

Reporting Official:

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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		X	X	X	X	X			AlloWrap (DS, Dry)
Blood Vessel												
Bone			X		X	X	X	X	X			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			X		X	X	X	X	X			***See full text on next page.
Cornea												
Dura Mater												
Embryo												
Fascia			X		X	X	X	X	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			X		X	X	X	X	X			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			X		X	X	X	X	X			***See full text on next page.
Tendon			X		X	X	X	X	X			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

FDA information collection OMB Control number: 0910-0543, expiration date: 6/30/2020

Additional Information: The version of eHCTERS released on November 9, 2018 required establishments to only include 361 HCT/Ps (HCT/Ps described in §1271.10). eHCTERS is no longer used for HCT/Ps regulated as drugs, devices, and/or biological products under 21 CFR Parts 207 or 807.

Previously listed HCT/Ps regulated as Medical Devices (ReConnex Pre-Sutured Tendon; AlloFuse DBM Gel and Putty; and AlloFuse Plus DBM Putty and Paste) are now listed exclusively with CDRH under AlloSource's medical device listing.

Previously listed HCT/Ps regulated as Biological Drugs (Vascular Grafts) are no longer listed, as these products are being manufactured under an investigational new drug application (IND) (21 CFR Part 312), and therefore do not require listing.

Proprietary Name(s):

Bone	AlloFuse (Cortical Fibers, Fiber Boat, Select CM, Cervical Spacer), AlloFlex, AlloGro, AlloPac
Cartilage	DeNovo NT, Osteochondral Allograft Kit, ProChondrix (Fresh, CR)
Skin	PureSkin, AlloSkin (RT, AC), AlloMend, ProLayer

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