

| | | | | |
|--|--|------------------------|--|---|
| <p>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</p> | | <p>FEI: 3000215346</p> | <p>Other FDA Registrations: Blood: Devices: FEI: 3000215346 Drugs:</p> | <p>Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2026 Last Registration Receipt Date: 12/12/2025 Summary Report Print Date: 12/15/2025</p> |
|--|--|------------------------|--|---|

| | | | | |
|---|--|--|--|---|
| <p>Legal Name and Location: AlloSource 6278 South Troy Circle Centennial, Colorado 80111 USA Phone: 720-873-0213</p> | | <p>Reporting Official: Trevor Wright, Director of Regulatory Affairs 6278 South Troy Circle Centennial, Colorado 80111 USA Phone: 720-873-0213 Ext. twright@allosource.org</p> | | <p>Satellite Recovery Establishment: No Parent Manufacturing Establishment FEI No.: Testing For Micro-Organisms Only: No</p> <p>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)).</p> |
| <p>Ext.:</p> | | | | |

| 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, AlloWrap 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 | | | AlloConnex |
| Heart Valve | | | | | | | | | | | | |
| HPC Apheresis | | | | | | | | | | | | |
| HPC Cord Blood | | | | | | | | | | | | |
| Ligament | | | X | | X | X | X | X | X | | | AlloConnex |
| 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 | | | | ***See full text on next page. |
| Tendon | | | X | | X | X | X | X | X | | | AlloConnex |
| Testicular Tissue | | | | | | | | | | | | |
| Tooth Pulp | | | | | | | | | | | | |
| Umbilical Cord Tissue | | | | | | | | | | | | |

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 are now listed exclusively with CDRH under AlloSource's medical device listing.

| | |
|-----------------------------|---|
| Proprietary Name(s): | |
| Bone | AlloFuse Fibers, AlloFuse Fiber Boat, AlloFuse Micro Fibers, AlloFuse Select CM, AlloFuse Cervical Spacer, AlloFlex, AlloGro, AlloPac, CanPac, AcuPac |
| Cartilage | DeNovo NT, Osteochondral Allograft Kit, ProChondrix CR |
| Skin | PureSkin, AlloSkin, AlloSkin AC, AlloMend, AlloMend UT (Ultra Thick), AlloMend Duo, ProLayer, Puregraft Essence |

FEI: 3000215346

Legal Name:

AlloSource