

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: 3005880024	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2024 Last Registration Receipt Date: 11/22/2023 Summary Report Print Date: 12/01/2023
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Legal Name and Location: OneLegacy - Orange 500 City Parkway West, Suite 110 Orange, California 92868 USA Phone: 213-989-2405 Ext.:	Reporting Official: Blanca M Cohen, Director, Quality Systems 1303 W. Optical Drive Azusa, California 91702 USA Phone: 213-229-5676 Ext. bcohen@onelegacy.org	Satellite Recovery Establishment: Yes Parent Manufacturing Establishment FEI No.: 3010307860 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)).
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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												
Blood Vessel		X	X									
Bone		X	X									
Cardiac Tissue - non-valved												
Cartilage		X	X									
Cornea		X	X									
Dura Mater												
Embryo												
Fascia		X	X									
Heart Valve		X	X									
HPC Apheresis												
HPC Cord Blood												
Ligament		X	X									
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X	X									
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	X									
Semen												
Skin		X	X									
Tendon		X	X									
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3005880024

Legal Name:

OneLegacy - Orange