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: 3010307860

Other FDA Registrations:
Blood:
Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2025 Last Registration Receipt Date: 12/17/2024 Summary Report Print Date: 12/20/2024

No

Legal Name and Location:

Azusa, California 91702

Phone: 213-229-5600

OneLegacy 1303 W. Optical Drive

USA

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:

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)).

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

Additional Information:	No additional information provided.
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Proprietary Name(s):

FEI: 3010307860 Legal Name: OneLegacy