## 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: 3005880024

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

Legal Name and Location:

OneLegacy - Orange

USA

500 City Parkway West, Suite 110

Orange, California 92868

Phone: 213-989-2405

Reporting Official:

Blanca M Cohen, Director, Quality Systems

1303 W. Optical Drive

Azusa, California 91702

LISA

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)).

Pnone: 213-989-2405	EXI											
	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		Х	Х									
Cardiac Tissue - non-valved												
Cartilage		х	Х									
Cornea		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

Proprietary Name(s):

FEI: 3005880024 Legal Name: OneLegacy - Orange