

Certifies that the Institution named below

ONELEGACY Los Angeles, CA

has met the association's Medical Standards and accreditation requirements and is hereby accredited for the following eye bank functions

Recovery, Processing, Tissue Storage, Final Distribution, Tissue Evaluation, and Donor Eligibility Determination

Effective Dates

June 18, 2020 – November 30, 2023

Chair, Board of Directors

President & CEO

Accreditation # 0020101

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: 2020

Last Registration Receipt Date: 12/18/2019 Summary Report Print Date: 01/07/2020

Legal Name and Location:

OneLegacy 221 S. Figueroa Street Suite 500

Los Angeles, California 90012

USA

Phone: 213-229-5600

Reporting Official:

Blanca M Cohen, Director, Quality Systems

221 S. Figueroa Street

Suite 500

Los Angeles, California 90012

USA

Phone: 213-229-5676 Ext. bcohen@onelegacy.org

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)).

		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		x	Х									
Bone		х	Х									
Cardiac Tissue - non-valved												
Cartilage		х	Х									
Cornea		х	Х		Х	х	Х	Х	Х			
Dura Mater												
Embryo												
Fascia		х	Х									
Heart Valve		х	Х									
HPC Apheresis												
HPC Cord Blood												
Ligament		X	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		x	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