## 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: 3000215345

Other FDA Registrations:

Blood: Devices: Drugs:

Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2019 Last Registration Receipt Date: 12/13/2018 Summary Report Print Date: 12/19/2018

Legal Name and Location:

New Mexico Lions Eye Bank / KeraLink - Southwest

2501 Yale Boulevard SE

Suite 100

Albuquerque, New Mexico 87106

Phone: 505-266-3937

Ext.:

Reporting Official:

Connie J Jones, VP, Quality, Regulatory, Compliance

5520 Research Park Drive

Suite 400

Baltimore, Maryland 21228

Phone: 770-855-4368 Ext.

cjones@keralink.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)).

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

Additional Information:

No additional information provided.

Proprietary Name(s):

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