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: 3001617760

Other FDA Registrations: Blood: FEI: 3001617760

Devices: Drugs: Reason For Last Submission: Annual Registration/Listing

Last Annual Registration Year: 2024 Last Registration Receipt Date: 12/19/2023 Summary Report Print Date: 01/05/2024

No

No

Legal Name and Location:

Bloodworks

701 Southwest 39th Street

Denter Westington 00057

Renton, Washington 98057

USA

Phone: 206-689-6287

Reporting Official:

Jessica D Hernandez, Regulatory Affairs Specialist

921 Terry Ave

Seattle, Washington 98104

LISA

Phone: 206-689-6287 Ext. Regulatory@BloodworksNW.Org Satellite Recovery Establishment:

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only:

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)).

	Donor Type(s)		Establishment Functions								 I	
HCT/P(s)		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)
Amniotic Membrane				Х								
Blood Vessel				Х								
Bone				X								
Cardiac Tissue - non-valved				X								
Cartilage				X								
Cornea				X								
Dura Mater												
Embryo												
Fascia				x								
Heart Valve				х								
HPC Apheresis	Autologous, Family Related			х								
HPC Cord Blood	Autologous, Family Related			x								
Ligament				x								
Nerve Tissue				x								
Oocyte	Anonymous, Directed, SIP			x								
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium				х								
Peripheral Blood Mononuclear Cells	Autologous			х								
Peritoneal Membrane												
Sclera				х								
Semen	Anonymous, Directed, SIP			х								
Skin				х								
Tendon				х								
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										06-MAR-20		

Additional Information:	No additional information provided

Proprietary Name(s):

FEI: 3001617760 Legal Name: Bloodworks