DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION

Legal Name and Location:

Seattle, Washington 98104

Phone: 206-689-6287

Bloodworks

USA

921 Terry Avenue

ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS **DESCRIBED IN 21 CFR 1271.10**

Ext.:

FEI: 0003071347

Other FDA Registrations: Blood: FEI: 0003071347

Drugs: FEI: 0003071347

Devices:

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

Jessica D Hernandez, Regulatory Affairs Specialist

QA/RA Department 921 Terry Ave

Reporting Official:

Seattle, Washington 98104

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

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Reason For Last Submission: Annual Registration/Listing

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)).

No

	Donor Type(s)		Establishment Functions									
HCT/P(s)		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												
Dura Mater												
Embryo												
Fascia												
Heart Valve												
HPC Apheresis	Autologous, Family Related	Х	Х	х	Х	Х	Х	Х	Х			
HPC Cord Blood	Autologous, Family Related						Х	Х	Х			
Ligament												
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin												
Tendon												
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue										06-MAR-20		

Additional Information:	No additional information provided
Additional information.	140 additional information provided.

Proprietary Name(s):

FEI: 0003071347 Legal Name: Bloodworks