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HUMAN CELL AND TISSUE ESTABLISHMENT REGISTRATION - Public Query Establishment Details

Establishment Name and Location

Current Status: Registered

Last Annual Registration Year: 2024

FDA Establishment Identifier (FEI): 1000477683

Establishment Name: Eurofins Donor & Product Testing, Inc. Denver

Address: 6933 South Revere Parkway

City: Centennial
State: Colorado
Zip: 80112

Country: UNITED STATES

Phone: 855-875-5227 ext. 803

Establishment Functions

Types of HCT/Ps	Recover	Screen	Donor Testing Package		Process	Store	Label	Distribute
Amniotic Membrane			€		ے			
Blood Vessel			€		V			
Bone			€		V			
Cardiac Tissue - non-valved			€		V			
Cartilage			€		V			
Cornea			€		V			
Dura Mater			€		V			
Embryo			€ í		V			
Fascia			€		V			
Heart Valve			€		V			
HPC Apheresis			€ í		V			
HPC Cord Blood			€ í		V			
Ligament			€		V			
Nerve Tissue			 ✓		V			
Oocyte			<u></u>		V			
Ovarian Tissue			€		V			
Pancreatic Islet Cells - autologous			€		V			
Parathyroid			∀		V			
Pericardium			∀		V			
Peripheral Blood Mononuclear Cells			€		V			
Peritoneal Membrane			€ í		V			
Sclera			€		ے			
Semen			€		ے			
Skin			€		V			
Tendon			ے		V			

Testicular Tissue	€	€	
Tooth Pulp	€	€	
Umbilical Cord Tissue	√	√	

Establishment HCT/P Listing

Types of HCT/Ps	HCT/Ps Described in 21 CFR 1271.10	Proprietary Names
Amniotic Membrane	X	
Blood Vessel	X	
Bone	X	
Cardiac Tissue - non-valved	X	
Cartilage	X	
Cornea	X	
Dura Mater	X	
Embryo	X	
Fascia	X	
Heart Valve	X	
HPC Apheresis	X	
HPC Cord Blood	X	
Ligament	X	
Nerve Tissue	X	
Oocyte	X	
Ovarian Tissue	X	
Pancreatic Islet Cells - autologous	X	
Parathyroid	X	
Pericardium	X	
Peripheral Blood Mononuclear Cells	X	
Peritoneal Membrane	X	
Sclera	X	
Semen	X	
Skin	X	
Tendon	X	
Testicular Tissue	X	
Tooth Pulp	X	
Umbilical Cord Tissue	X	

HCT/P Listing - Donor Information

Types of HCT/Ps	SIP	Directed	Anonymous	Autologous	Family Related
Embryo	\mathbf{V}	lacksquare	ے		
HPC Apheresis				ے	ے
HPC Cord Blood				ے	ے
Oocyte	€	€	ے		
Peripheral Blood Mononuclear Cells				ے	ے
Semen	ے	√	 ✓		

Print Date: 02/13/2024

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