

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: 3000719528	Other FDA Registrations: Blood: Devices: Drugs:	Reason For Last Submission: Annual Registration/Listing Last Annual Registration Year: 2023 Last Registration Receipt Date: 11/21/2022 Summary Report Print Date: 12/01/2022
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Legal Name and Location: Center for Organ Recovery & Education (CORE) 204 Sigma Drive RIDC Park Pittsburgh, Pennsylvania 15238 USA Phone: 412-963-3550 Ext.:	Reporting Official: Nicholas Yakubisin, Associate Director of Quality Systems 204 Sigma Drive RIDC Park Pittsburgh,, Pennsylvania 15238 USA Phone: 412-963-3550 Ext. nyakubisin@core.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)).
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HCT/P(s)	Donor Type(s)	Establishment Functions								Date of Discontinuance	Date of Resumption	Proprietary Name(s)
		Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute			
Amniotic Membrane												
Blood Vessel		X	X	X	X		X	X				
Bone		X	X	X	X		X	X				
Cardiac Tissue - non-valved												
Cartilage		X	X	X	X		X	X				
Cornea		X	X	X	X	X	X	X	X			
Dura Mater												
Embryo												
Fascia		X	X	X	X		X	X				
Heart Valve		X	X	X	X		X	X				
HPC Apheresis												
HPC Cord Blood												
Ligament		X	X	X	X		X	X				
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium		X	X	X	X		X	X				
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera		X	X	X	X	X	X	X	X			
Semen												
Skin		X	X	X	X		X	X				
Tendon		X	X	X	X		X	X				
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3000719528

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