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: 2024 Last Registration Receipt Date: 12/08/2023 Summary Report Print Date: 12/15/2023		
Legal Name and Location: Center for Organ Recovery & Education (CORE) 204 Sigma Drive RIDC Park Pittsburgh, Pennsylvania 15238 USA Phone: 412-963-3550 <b>Ext.:</b>				Reporting Official: Julie Leblanc-Cmar, Director of Quality Systems 204 Sigma Dr RIDC Park Pittsburgh, Pennsylvania 15238 USA Phone: 412-963-3550 Ext. 2067 jleblanc-cmar@core.org						Satellite Recovery Establishment: No   Parent Manufacturing Establishment FEI No.: 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)).			
				Establishment Functions									
HCT/P(s)	Donor Type(s)	Recover	Screen	Donor Testing	Package	Process	Store	Label	Distribute	Date of Discontinuance	Date of Resumption	Proprietary Name(s)	
Amniotic Membrane													
Blood Vessel		x	х	x	х		x	х					
Bone		x	х	х	х		x	х					
Cardiac Tissue - non-valved													
Cartilage		x	х	x	х		x	х					
Cornea		x	х	х	х	х	х	х	х				
Dura Mater													
Embryo													
Fascia		x	х	х	х		x	х					
Heart Valve		x	х	х	x		х	х					
HPC Apheresis													
HPC Cord Blood													
Ligament		x	х	х	x		х	х					
Nerve Tissue													
Oocyte													
Ovarian Tissue													
Pancreatic Islet Cells - autologous													
Parathyroid													
Pericardium		x	х	х	х		х	х					
Peripheral Blood Mononuclear Cells													
Peritoneal Membrane													
Sclera		х	х	Х	х	х	х	Х	х				
Semen													
Skin		х	х	Х	х		х	Х					
Tendon		х	х	Х	х		х	Х					
Testicular Tissue													
Tooth Pulp													
Umbilical Cord Tissue													

Legal Name:

Additional Information: No additional information provided.

Proprietary Name(s):

FEI: 3000719528

Legal Name:

Center for Organ Recovery & Education (CORE)