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: 3009234552

Other FDA Registrations: Blood:

Devices:

Drugs:

Reason For Last Submission: Annual Registration/Listing
Last Annual Registration Year: 2025
Last Registration Receipt Date: 12/04/2024
Summary Report Print Date: 12/05/2024

Legal Name and Location:

CellRight Technologies 1808 Universal City Blvd Reporting Official:
Lance Johnson, VP of Quality/Reg
1808 Universal City Blvd
Universal City, Texas 78148
USA

Satellite Recovery Establishment: No

Parent Manufacturing Establishment FEI No.:

Testing For Micro-Organisms Only: No

Universal City, Texas 78148

USA

Phone: 210-659-9353

Ext.:

Phone: 512-775-7610 Ext. ljohnson@cellrighttechnologies.com

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									i	
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			Х		Х	Х	х	Х	Х	AmnioWorks		
Blood Vessel												
Bone			Х		Х	х	Х	Х	Х			***See full text on next page.
Cardiac Tissue - non-valved												
Cartilage			Х				Х					
Cornea												
Dura Mater												
Embryo												
Fascia			Х		X	x	Х	Х	X			
Heart Valve												
HPC Apheresis												
HPC Cord Blood												
Ligament			Х		х	х	Х	Х	х			
Nerve Tissue												
Oocyte												
Ovarian Tissue												
Pancreatic Islet Cells - autologous												
Parathyroid												
Pericardium												
Peripheral Blood Mononuclear Cells												
Peritoneal Membrane												
Sclera												
Semen												
Skin			Х		х	х	Х	Х	Х			***See full text on next page.
Tendon			Х		Х	Х	Х	Х	Х			
Testicular Tissue												
Tooth Pulp												
Umbilical Cord Tissue												

Additional Informatio	tion: This site has a new warehouse (2021) location directly adjacent to the main building. The warehouse (located at 1740 Universal City Blvd. Universal City TX 78148) is under the same quality management system and management team. At the request of CBER this address was not registered. Both locations are expected to be audited at the same time.							
Proprietary Name(s):	Bone	MatrixOI, FlexIT, InFill AFM, Influx, MatrixCellect 100 DBM Putty, MatrixCellect 100 DBM Crunch, ConCelltrate 100, DentalFix, AlloSync						
	Skin	MatrixND Dermis, DermaPure, Dermis on Demand, VNEW, Esano ADM						

Legal Name: CellRight Technologies 3009234552 FEI: