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: 2024 Last Registration Receipt Date: 11/16/2023 Summary Report Print Date: 12/01/2023

Legal Name and Location:

CellRight Technologies 1808 Universal City Blvd

Ext.:

Universal City, Texas 78148 USA

Phone: 210-659-9353

Reporting Official:

Lance Johnson, VP of Quality/Reg 1808 Universal City Blvd Universal City, Texas 78148

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

		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			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		х	x	Х	Х	х			
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												

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Skin

Legal Name: CellRight Technologies 3009234552 FEI:

MatrixND Dermis, DermaPure, Dermis on Demand, VNEW, Esano ADM