

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 (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3009234552	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input checked="" type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:19-NOV-2015 DISTRICT: Dallas PRINTED BY FDA:03-DEC-2015
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION													14. PROPRIETARY NAME(S)	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps									11. HCT/Ps DESCRIBED IN 21 CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS DRUGS OR BIOLOGICAL DRUGS			
	Establishment Functions														
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute						
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) CellRight Technologies, LLC 1808 Universal City Blvd Universal City, Texas 78148 a. PHONE 210-659-9353 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone		X		X	X	X	X	X	X				*** See full text on next page	
	b. Cartilage														
	c. Cornea														
	d. Dura Mater														
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	f. Fascia			X		X	X	X	X	X	X				
	g. Heart Valve														
	h. Ligament			X		X	X	X	X	X	X				
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	j. Pericardium			X		X	X	X	X	X	X				
5. ENTER CORRECTIONS TO ITEM 4 6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) CellRight Technologies, LLC Attn: Robin M. Sullivan, DC, CTBS 1808 Universal City Blvd Universal City, Texas 78148 a. PHONE 210-659-9353 EXT _____	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	l. Sclera														
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous														
	n. Skin			X		X	X	X	X	X				MatrixIQ Dermis	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	p. Tendon			X		X	X	X	X	X	X				
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic														
	r. Vascular Graft														
	7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____ 8. U.S. AGENT a. E-MAIL _____	s.													
		t.													
u.															
v.															
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Robin M. Sullivan, DC, CTBS b. E-MAIL rsullivan@cellrighttechnologies.com c. TITLE VP of Regulatory Affairs d. DATE 18-NOV-2015															

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 (HCT/Ps)**
(See reverse side for instructions)

1. REGISTRATION NUMBER
(FDA Establishment Identifier)

FEI: 3009234552

2

ADDITIONAL INFORMATION:

Proprietary Name(s):

- a. Bone MatrixOI, FlexIT, Influx, MatrixCollect 100 DBM
Putty, MatrixCollect 100 DBM Crunch, ConCelltrate
100