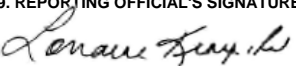


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 3004557352	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:16-NOV-2017 DISTRICT: Atlanta PRINTED BY FDA:27-JAN-2018
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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				
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	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) We Are Sharing Hope SC 164-B Lott Court W. Columbia, South Carolina 29169 a. PHONE 843-763-7755 EXT _____ b. <input checked="" type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 3003935893) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone	X	X		X					X						
	b. Cartilage	X	X		X					X						
	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					
	g. Heart Valve	X	X		X					X	X					
	h. Ligament	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					
	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					
	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					
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic															
	r. Vascular Graft	X	X		X					X	X					
	s.															
	t.															
	u.															
	v.															
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) We Are Sharing Hope SC Attn: Lorraine Kemp, RN, MSN 3950 Faber Place Drive Suite 400 Charleston, South Carolina 29405 a. PHONE 843-725-5526 EXT _____																
7. ENTER CORRECTIONS TO ITEM 6 a. PHONE _____ EXT _____ b. PHONE _____																
8. U.S. AGENT a. E-MAIL _____																
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Lorraine Kemp, RN, MSN b. E-MAIL kempl@sharinghopesc.org c. TITLE Director Quality Systems d. DATE 16-NOV-2017																

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: 3004557352

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ADDITIONAL INFORMATION:

Opened Dedicated Recovery Suite in August 2017 at the Columbia site.

Proprietary Name(s):