See Instructions for OMB Statement. FORM APPROVED:OMB No.0910-0543. Expiration Date: 3/31/2017

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,

1. REGISTRATION NUMBER	2. REASON FOR SUBMISSION							
(FDA Establishment Identifier)	a. INITIAL REGISTRATION / LISTING							
FEI: 3000215344	b. X ANNUAL REGISTRATION / LISTIN							
· Li. 3000213344	CHANGE IN INFORMATION							

	VALIDATIONFOR FDA USE ONLY	1
	VALIDATED BY FDA:20-DEC-2016	
G	DISTRICT: Denver	
	PRINTED BY FDA:28-DEC-2016	

AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps (See reverse side for instructions)	c. CHANGE IN INFORMATION d. INACTIVE													
PART I - ESTABLISHMENT INFORMATION	RODUCT INFOR	DDUCT INFORMATION								유류:	돌유12	무무요3		
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											SE E	OF OF SECULAR	
a. BLOOD FDA 2830 NO		Establishment Functions								7Ps IBED 71.10	ATE 7/Ps	SICA ATE OR	14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO	Types of HCT / Ps		HCT / Ps Recover So	cover Screen Test Package		Package	Process Store		Label	Distribute	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	(0)
c. DRUG FDA 2656 NO													o,	
 PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) 	a. Bone		X	X							X			
DCI Donor Services dba New Mexico Donor Services	b. Cartilage		X	X							X			
1609 University Blvd. NE Albuquerque, New Mexico 87102	c. Cornea													
	d. Dura Mater													
a. PHONE 877-401-2511 EXT 5307	e. Embryo	SIP Directed Anonymous												
b. X SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. 1000307504 c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia		X	X							X			
5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve		X	X							X			
	h. Ligament	_	X	X							X			
MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) New Mexico Donor Services Attn: Stephanie Cozby	i. Oocyte	SIP Directed Anonymous												
	j. Pericardium		X	X							X			
1609 University Blvd. NE Albuquerque, New Mexico 87102	k. Peripheral Blood Stem	Autologous Family Related Allogeneic												
	I. Sclera													
a. PHONE 505-353-5343 EXT	m. Semen	SIP Directed Anonymous												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	n. Skin	Anonymous	X	X							X			
	o. Somatic Cell Therapy Products	Autologous Family Related Allogeneic												
8. U.S. AGENT	p. Tendon		X	X							X			
	q. Umbilical Cord Blood	□ Autologous □ Family Related □ Allogeneic												
a. E-MAIL	r. Vascular Graft		X	X							X			
9. REPORTING OFFICIAL'S SIGNATURE	S.													
a. TYPED NAME Stephanie Cozby	t.													
b. E-MAIL scozby@dcids.org	u.													
c. TITLE Director of Quality and Compliance d. DATE 19-DEC-2016	v.													