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, AND CELLULA AND TISSUE BASED BROUNTS (HCT/Ps)

(FDA Establishment Identifier) FEI: 0002275064

1. REGISTRATION NUMBER

2. REASON FOR SUBMISSION a. INITIAL REGISTRATION / LISTING b. X ANNUAL REGISTRATION / LISTING c. CHANGE IN INFORMATION

VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:06-DEC-2016 DISTRICT: New Jersey PRINTED BY FDA:15-DEC-2016

(See reverse side for instructions)	5)	d. NACTIVE												
PART I - ESTABLISHMENT INFORMATION	PART II - P	PART II - PRODUCT INFORMATION									₽ ₽ ₽ 2	돌유12 -	BRR3	
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps 기원 기계													
a. BLOOD FDA 2830 NO. FEI: 0002275064		Establishment Functions								/Ps IBED 71.10	PATE S	ATE S	14. PROPRIETARY NAME(S)	
b. DEVICES FDA 2891 NO.	Types of HCT / Ps		Recover	Screen	Test	Package	ckage Process S	Store	e 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	(5)
c. DRUG FDA 2656 NO													Š	
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)	a. Bone													
Bergen Community Regional Blood Center dba Community Blood Services	b. Cartilage													
Elie Katz Umbilical Cord Blood Program New Jersey Cord Blood Bank (NJCBB)	c. Cornea													
102 Chestnut Ridge Road	d. Dura Mater													
Montvale, New Jersey 07645 a. PHONE 201-444-3900 EXT	e. Embryo	SIP Directed Anonymous												
b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. c. TESTING FOR MICRO-ORGANISMS ONLY	f. Fascia													
c. L TESTING FOR MICRO-ORGANISMS ONLY 5. ENTER CORRECTIONS TO ITEM 4	g. Heart Valve													
	h. Ligament													
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Blood Systems, Inc. Attn: Gina Ramirez 6210 East Oak Street P.O.Box 1867 Scottsdale, Arizona 85252-1867	i. Oocyte	SIP Directed Anonymous												
	j. Pericardium													
	k. Peripheral Blood Stem	X Autologous X Family Related X Allogeneic	X	X	X	X	X	X	X	X	X		X	
	I. Sclera													
a. PHONE 303-363-2221 EXT 7. ENTER CORRECTIONS TO ITEM 6 b. PHONE	m. Semen	SIP Directed Anonymous												
	n. Skin	Anonymous												
	o. Somatic Cell Therapy Products	X Autologous X Family Related Allogeneic	x	x	X	x	X	X	X		X		X	
8. U.S. AGENT	p. Tendon	-												
	q. Umbilical Cord Blood	X Autologous X Family Related X Allogeneic	x	X	X	X	X	X	X	X	X		X	
a. E-MAIL	r. Vascular Graft													
9. REPORTING OFFICIAL'S SIGNATURE	s. Therapeutic Cells		X	X					X				X	
a. TYPED NAME Gina Ramirez	t.													
b. E-MAIL gramirez@bloodsystems.org	u.													
c. TITLE Regulatory Manager d. DATE 05-DEC-2016	V.													