

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: 3001239138	2. REASON FOR SUBMISSION a. <input type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input type="checkbox"/> ANNUAL REGISTRATION / LISTING c. <input checked="" type="checkbox"/> CHANGE IN INFORMATION d. <input type="checkbox"/> INACTIVE	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA: 23-FEB-2017 DISTRICT: Seattle PRINTED BY FDA: 27-FEB-2017
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION								11. HCT/PS DESCRIBED IN 21 CFR 1271.10	12. HCT/PS REGULATED AS MEDICAL DEVICES	13. HCT/PS REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)
3. OTHER FDA REGISTRATIONS	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
	Types of HCT / Ps	Establishment Functions										
		Recover	Screen	Test	Package	Process	Store	Label	Distribute			
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone		X							X		
	b. Cartilage		X							X		
	c. Cornea	X	X		X	X	X	X	X	X		
	d. Dura Mater											
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia		X							X		
	g. Heart Valve		X							X		
	h. Ligament		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		
	k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	l. Sclera	X	X		X	X	X	X	X	X		
	m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	n. Skin		X							X		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	p. Tendon		X							X		
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
	r. Vascular Graft		X							X		
	s. Nerve Tissue		X							X		
	t. Peritoneal Membrane		X							X		
	u.											
	v.											

4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code)
 Lions VisionGift
 2201 SE 11th Ave.
 Portland, Oregon 97214

a. PHONE 503-808-7070 EXT _____
 b. SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____)
 c. TESTING FOR MICRO-ORGANISMS ONLY


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)
 Lions VisionGift
 Attn: Kristin J. Mathes, MA
 2201 SE 11th Ave.
 Portland, Oregon 97214

a. PHONE 5038087026 EXT _____
 b. PHONE _____

8. U.S. AGENT

a. E-MAIL

9. REPORTING OFFICIAL'S SIGNATURE

 a. TYPED NAME Kristin J. Mathes, MA
 b. E-MAIL kristin@visiongift.org
 c. TITLE Chief Quality & Regulatory Officer
 d. DATE 22-FEB-2017