

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: 3005234844	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:08-FEB-2018 DISTRICT: Seattle PRINTED BY FDA:15-FEB-2018
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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 DRUGS OR 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				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Lattice Biologics Ltd 512 E Madison Ave. Suite A1 Belgrade, Montana 59714 a. PHONE 480-563-0800 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			
	b. Cartilage		X		X	X	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	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	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												
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Lattice Biologics, Inc. Attn: Kiara Pineda 512 E Madison Ave. Suite A1 Belgrade, Montana 59714 a. PHONE 480-563-0800 EXT _____	n. Skin		X		X	X	X	X	X	X			
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic												
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	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												
8. U.S. AGENT a. E-MAIL _____	s. Amniotic Membrane		X		X	X	X	X	X	X			
	t. Amniotic Fluid		X		X	X	X	X	X	X			
	u.												
	v.												
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Kiara Pineda b. E-MAIL kpineda@latticebiologics.com c. TITLE Quality Manager d. DATE 07-FEB-2018													