

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION <b>ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,                  AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps)</b> (See reverse side for instructions)	<b>1. REGISTRATION NUMBER</b> (FDA Establishment Identifier)  FEI: 3006185361	<b>2. REASON FOR SUBMISSION</b> 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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:16-NOV-2016 DISTRICT: Denver PRINTED BY FDA:15-DEC-2016
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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				
	Establishment Functions																
	Types of HCT / Ps																
	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Joint Restoration Foundation DBA JRF Ortho  6746 S Revere Pkwy Suite B-125 Centennial, Colorado 80112  a. PHONE 877-255-6727 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					
	b. Cartilage											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				
	g. Heart Valve																
	h. Ligament												X	X			
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	j. Pericardium																
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																	
<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) JRF Ortho Attn: Dina Pasquino, CTBS 6746 S Revere Pkwy Suite B-125 Centennial, Colorado 80112  a. PHONE 877-255-6727 EXT _____	n. Skin																
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
<b>7. ENTER CORRECTIONS TO ITEM 6</b>	p. Tendon											X	X				
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
<b>8. U.S. AGENT</b>  a. E-MAIL _____	r. Vascular Graft																
	s.																
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Dina Pasquino, CTBS b. E-MAIL dpasquino@jrfortho.org c. TITLE Director of Business Operations	t.																
	u.																
	v.																
d. DATE 15-NOV-2016																	