

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> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 3007220913	<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	VALIDATION--FOR FDA USE ONLY VALIDATED BY FDA:12-NOV-2008 DISTRICT: New Orleans PRINTED BY FDA:14-NOV-2008
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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											
	<i>Establishment Functions</i>											
	Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. FEI: 3000718968 b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	a. Bone			X						X		
4. PHYSICAL LOCATION <i>(Include legal name, number and street, city, state, country, and post office code)</i> Research & Diagnostic Laboratories, Inc. 4402 Terrace View Rd. Louisville, Tennessee 37777  a. PHONE 865-273-6019 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	b. Cartilage			X						X		
	c. Cornea			X						X		
	d. Dura Mater											
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia			X							X	
5. ENTER CORRECTIONS TO ITEM 4  6. MAILING ADDRESS OF REPORTING OFFICIAL <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Research & Diagnostic Laboratories, Inc. Attn: Ernest W. Fuson 4402 Terrace View Rd. Louisville, Tennessee 37777  a. PHONE 865-977-5598 EXT _____	g. Heart Valve			X						X		
	h. Ligament			X						X		
	i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X							X	
	j. Pericardium			X						X		
	k. Peripheral Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X							X	
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____	l. Sclera			X						X		
	m. Semen <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous			X						X		
	n. Skin			X						X		
	o. Somatic Cell Therapy Products <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic			X							X	
	8. U.S. AGENT  a. E-MAIL _____	p. Tendon			X						X	
q. Umbilical Cord Blood Stem Cells <input checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic				X						X		
r. Vascular Graft				X						X		
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Ernest W. Fuson b. E-MAIL ewfuson@aol.com c. TITLE Laboratory Director d. DATE _____	s.											
	t.											
	u.											
	v.											

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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)*

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**ADDITIONAL INFORMATION:**

Testing laboratory only.

**Proprietary Name(s):**