


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) <small>(See reverse side for instructions)</small>	1. REGISTRATION NUMBER <small>(FDA Establishment Identifier)</small> FEI: 3003420280	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:13-JAN-2017 DISTRICT: Atlanta PRINTED BY FDA:03-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 DRUGS OR BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)																			
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps <table border="1" style="width:100%; border-collapse: collapse;"> <thead> <tr> <th rowspan="2">Types of HCT / Ps</th> <th colspan="9">Establishment Functions</th> </tr> <tr> <th>Recover</th> <th>Screen</th> <th>Test</th> <th>Package</th> <th>Process</th> <th>Store</th> <th>Label</th> <th>Distribute</th> <th></th> </tr> </thead> </table>	Types of HCT / Ps	Establishment Functions									Recover	Screen	Test	Package	Process	Store	Label	Distribute					
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) Xytex Laboratories 730 Peachtree Street NE Suite 675 Atlanta, Georgia 30308 a. PHONE 404-881-0426 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone																							
	b. Cartilage																							
	c. Cornea																							
	d. Dura Mater																							
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																							
	f. Fascia																							
	g. Heart Valve																							
	h. Ligament																							
	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 checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X		X	X	X	X	X	X														
	n. Skin																							
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																							
p. Tendon																								
q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																								
r. Vascular Graft																								
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME James T. Spradlin, M.D. b. E-MAIL tspradlin@xytex.com c. TITLE Chief Medical & Laboratory Director d. DATE 12-JAN-2017 	s.																							
	t.																							
	u.																							
	v.																							