


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: 1000122198		<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:29-DEC-2016 DISTRICT: Philadelphia PRINTED BY FDA:09-JAN-2017							
<b>PART I - ESTABLISHMENT INFORMATION</b>		<b>PART II - PRODUCT INFORMATION</b>						11. HCT/Ps CFR 1271.10	12. HCT/Ps REGULATED AS MEDICAL DEVICES	13. HCT/Ps REGULATED AS BIOLOGICAL DRUGS	14. PROPRIETARY NAME(S)		
<b>3. OTHER FDA REGISTRATIONS</b> a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. FEI: 0002247110		<b>10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps</b>											
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) WuXi AppTec Inc.  4751 League Island Blvd. (Contract Manufacturing) Philadelphia, Pennsylvania 19112  a. PHONE 215-218-5500 EXT _____ b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		<b>Establishment Functions</b>											
		Types of HCT / Ps		Recover	Screen	Test	Package					Process	Store
<b>5. ENTER CORRECTIONS TO ITEM 4</b>		a. Bone											
		b. Cartilage											
<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) WuXi AppTec Inc. Attn: Michael McCormick 4751 League Island Blvd. (Contract Manufacturing) Philadelphia, Pennsylvania 19112  a. PHONE 215-218-5543 EXT _____		c. Cornea											
		d. Dura Mater											
<b>7. ENTER CORRECTIONS TO ITEM 6</b>		e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		f. Fascia											
<b>8. U.S. AGENT</b>  a. E-MAIL _____		g. Heart Valve											
		h. Ligament											
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  09 Jan 17 a. TYPED NAME Michael McCormick b. E-MAIL michael.mccormick@wuxiapptec.com c. TITLE V.P., Quality Assurance d. DATE 28-DEC-2016		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 checked="" type="checkbox"/> Allogeneic					X	X	X			X	IND / Pre IND Client Product
		l. Sclera											
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
		n. Skin											
		o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic					X	X	X	X		X	IND / Pre IND Client Product
		p. Tendon											
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic					X	X	X	X		X	IND / Pre IND Client Product
		r. Vascular Graft											
		s. Amniotic Membrane					X	X	X	X	X		NuCel, ReNu
		t. Ovarian Tissue						X	X	X	X		IND / Pre IND Client Product
		u.											
		v.											