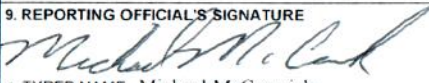


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (FDA Establishment Identifier) FEI: 1000122198	2. REASON FOR SUBMISSION 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:27-DEC-2017 DISTRICT: Philadelphia PRINTED BY FDA:27-JAN-2018									
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. FEI: 0002247110		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) WuXi AppTec Inc. 4751 League Island Blvd. (Contract Manufacturing) Philadelphia, Pennsylvania 19112 a. PHONE 215-218-7100 EXT 5543 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 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	X		IND / Pre IND Client Product
		u.											
		v.											
5. ENTER CORRECTIONS TO ITEM 4													
6. MAILING ADDRESS OF REPORTING OFFICIAL (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 215-218-7100 EXT 5543													
7. ENTER CORRECTIONS TO ITEM 6		b. PHONE _____											
8. U.S. AGENT													
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Michael McCormick b. E-MAIL michael.mccormick@wuxiapptec.com c. TITLE V.P., Quality Assurance d. DATE 27-DEC-2017													