

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: 3008865245	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:23-JUN-2017 DISTRICT: New Orleans PRINTED BY FDA:23-JUN-2017
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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								
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) NuTech Spine, Inc. 600 Luckie Drive Suite 315 Birmingham, Alabama 35223 a. PHONE 2053297285 EXT 405 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY	a. Bone						X		X	X	X					NuFix, SIFix, DuALIF	
	b. Cartilage						X		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	X							
	g. Heart Valve																
	h. Ligament							X		X	X						
	i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																
	j. Pericardium							X		X	X						
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) NuTech Spine and Biologics Attn: Rachel Cromer, AL 600 Luckie Drive Suite 315 Birmingham, Alabama 35223 a. PHONE 2053297285 EXT _____ b. PHONE _____	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																
	n. Skin						X		X	X						GammaGraft	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
	p. Tendon						X		X	X							
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																
	r. Vascular Graft																
	7. ENTER CORRECTIONS TO ITEM 6 8. U.S. AGENT a. E-MAIL _____	s.															
		t.															
u.																	
v.																	
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Rachel Cromer, AL b. E-MAIL rcromer@nutechspine.com c. TITLE Quality Director d. DATE 22-JUN-2017																	