

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: 3006638648	<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	<b>VALIDATION--FOR FDA USE ONLY</b> VALIDATED BY FDA:22-NOV-2017 DISTRICT: Baltimore PRINTED BY FDA:27-JAN-2018
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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																	
	Types of HCT / Ps	Establishment Functions								Recover					Screen	Test	Package	Process
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		a. Bone			X	X	X	X	X		X	X	X					
<b>4. PHYSICAL LOCATION</b> (Include legal name, number and street, city, state, country, and post office code) Osiris Therapeutics, Inc.  7015 Albert Einstein Drive Columbia, Maryland 21046  a. PHONE 443-545-1800 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	X	X	X	X	X	X							Cartiform, Menvivo
	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 type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																		
<b>5. ENTER CORRECTIONS TO ITEM 4</b>  <b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> (Include institution name if applicable, number and street, city, state, country, and post office code) Osiris Therapeutics, Inc. Attn: Sherry D. Elchin, MS 7015 Albert Einstein Dr. Columbia, Maryland 21046  a. PHONE 443-545-1832 EXT _____ b. PHONE _____	n. Skin																	
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
<b>8. U.S. AGENT</b>  a. E-MAIL _____	p. Tendon																	
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																	
	r. Vascular Graft																	
<b>9. REPORTING OFFICIAL'S SIGNATURE</b>  a. TYPED NAME Sherry D. Elchin, MS b. E-MAIL selchin@osiris.com c. TITLE VP, Technical Services d. DATE 21-NOV-2017	s. Placenta	X	X	X	X	X	X	X	X	X	X							*** See full text on next page
	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)**  
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**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

Placenta      Grafix PRIME, Grafix CORE, Grafix XC, Stravix,  
                    GrafixPL PRIME, GrafixPL CORE, StravixPL