

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: 3014469919	2. REASON FOR SUBMISSION a. <input checked="" type="checkbox"/> INITIAL REGISTRATION / LISTING b. <input 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:12-JUN-2018 DISTRICT: Int'l Operations Group PRINTED BY FDA:12-JUN-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	Store	Label	Distribute							
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) YGEIODORA MEDICAL CENTER LTD 8 Michael Karaoli & Byron Office 201, Anemomylos Building Nicosia, 1095 Cyprus a. PHONE 357-22-670850 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 checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X	X	X	X	X	X	X	X	X					
	f. Fascia															
	g. Heart Valve															
	h. Ligament															
	i. Oocyte <input checked="" type="checkbox"/> SIP <input checked="" type="checkbox"/> Directed <input checked="" type="checkbox"/> Anonymous	X	X	X	X	X	X	X	X	X	X					
	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	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	s.															
	t.															
a. TYPED NAME Stephanos N. Trokoudes, MBA, BA	u.															
b. E-MAIL strokoudes@pedieosivf.com.cy	v.															
c. TITLE International Business Development Mngr d. DATE 25-APR-2018																