

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: 0001570969	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:22-DEC-2017 DISTRICT: Cincinnati PRINTED BY FDA:27-JAN-2018
---	--	--	---

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				
	Types of HCT / Ps		Establishment Functions														
	Recover	Screen	Test	Package	Process	Store	Label	Distribute									
a. BLOOD FDA 2830 NO. <u>FEI: 0001570969</u> b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	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 checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic	X	X		X	X	X	X	X	X							
	l. Sclera																
	m. Semen <input checked="" type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous							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 checked="" type="checkbox"/> Autologous <input checked="" type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic						X	X	X	X	X						
	r. Vascular Graft																
	s. Pancreatic Islet Cells - autologous				X	X		X	X	X							
	t. Therapeutic Cells	X	X		X	X	X	X	X	X			X			Kymriah, Provenge	
	u.																
	v.																