

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: 1000512996	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:17-NOV-2017 DISTRICT: Baltimore PRINTED BY FDA:27-JAN-2018
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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		
	Types of HCT / Ps		Establishment Functions										
	Recover	Screen	Test	Package	Process	Store	Label	Distribute					
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 1000512996 c. DRUG FDA 2656 NO. _____	a. Bone	X			X	X	X	X	X				Chondrofix
	b. Cartilage	X			X	X	X	X	X				Chondrofix
	c. Cornea												
	d. Dura Mater												
	e. Embryo												
	f. Fascia	X								X			
	g. Heart Valve	X			X	X	X	X	X				CardioGraft
	h. Ligament	X								X			
	i. Oocyte												
	j. Pericardium	X								X			
	k. Peripheral Blood Stem												
	l. Sclera												
	m. Semen												
	n. Skin	X			X	X	X	X	X				*** See full text on next page
	o. Somatic Cell Therapy Products												
	p. Tendon	X								X			
	q. Umbilical Cord Blood												
	r. Vascular Graft	X			X	X	X	X	X				AngioGraft
	s. Cardiac Tissue - non-valved	X			X	X	X	X	X	X	X		CardioGraft, CardioGraft-MC
	t.												
	u.												
	v.												

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PUBLIC HEALTH SERVICE

FOOD AND DRUG ADMINISTRATION
**ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES,
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2

ADDITIONAL INFORMATION:

Proprietary Name(s):

n. Skin DermACELL, DermACELL AWM, ArthroFLEX,
ArthroFLEX BioWasher, OrACELL