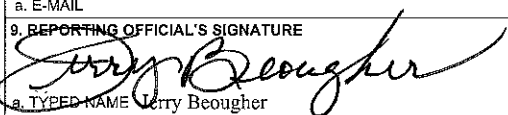


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 3008927553	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 1 VALIDATED BY FDA:04-OCT-2011 DISTRICT: Los Angeles PRINTED BY FDA:01-NOV-2011
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PART I - ESTABLISHMENT INFORMATION	PART II - PRODUCT INFORMATION			14. PROPRIETARY NAME(S)								
3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____	10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps											
	Types of HCT / Ps	Establishment Functions								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
	Recover	Screen	Test	Package	Process	Store	Label	Distribute				
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Pinnacle Transplant Technologies, LLC 1125 W. Pinnacle Peak Rd Bldg 2 Phoenix, Arizona 85027 a. PHONE 623-277-5400 EXT 404 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	X	X	X			
	b. Cartilage											
	c. Cornea											
	d. Dura Mater											
	e. Embryo <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
	f. Fascia		X	X	X	X	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) Pinnacle Transplant Technologies, LLC Attn: Jerry Beougher 1125 W. Pinnacle Peak Rd Bldg 2 Phoenix, Arizona 85027 a. PHONE 623-277-5400 EXT 504	g. Heart Valve											
	h. Ligament		X	X	X	X	X	X	X			
	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											
7. ENTER CORRECTIONS TO ITEM 6	n. Skin		X	X		X	X			X		
	o. Somatic Cell Therapy Products <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic											
8. U.S. AGENT a. E-MAIL 9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Jerry Beougher b. E-MAIL jbeougher@pinnacletransplant.com c. TITLE Chief Executive Officer d. DATE 03-OCT-2011	p. Tendon		X	X	X	X	X	X	X			
	q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input checked="" type="checkbox"/> Allogeneic							X		X	X	
	r. Vascular Graft											
	s.											
	t.											
	u.											
	v.											

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
(Field Establishment Identifier)

FEI: 3008927553

ADDITIONAL INFORMATION:

Skin is used as a process ingredient only and not processed for whole product distribution.

BioDfactor (tm) has been developed as a liquid wound covering product for use in vivo to fill soft tissue defects or bone voids. BioDfactor (tm) can be applied directly to the surgical site or mixed with the patients own blood to provide an easy to use wound covering offering the unique biologic structure of amniotic tissue.

The BioDfence (tm) patch has been developed as an in vivo wound covering to provide a physical barrier to protect tendons and nerves at the surgical site. It is sterile, easy to use, and available for a broad range of clinical applications.

Proprietary Name(s):