

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> <i>(See reverse side for instructions)</i>	<b>1. REGISTRATION NUMBER</b> (Field Establishment Identifier)  FEI: 1000100754	<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> 1 VALIDATED BY FDA:09-DEC-2011 DISTRICT: San Francisco PRINTED BY FDA:15-DEC-2011
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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																		
	<i>Establishment Functions</i>																		
		Recover	Screen	Test	Package	Process	Store	Label	Distribute										
a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. FEI: 3007215572 c. DRUG FDA 2656 NO. _____																			
<b>4. PHYSICAL LOCATION</b> <i>(Include legal name, number and street, city, state, country, and post office code)</i> Tissue Banks International National Processing Center 2597 Kerner Blvd. San Rafael, California 94901  a. PHONE 415-455-9000 EXT _____ 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	TranZgraft, See next page							
		b. Cartilage		X		X	X	X	X	X	X	TranZgraft							
		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		TranZgraft						
		<b>5. ENTER CORRECTIONS TO ITEM 4</b>																	
		<b>6. MAILING ADDRESS OF REPORTING OFFICIAL</b> <i>(Include institution name if applicable, number and street, city, state, country, and post office code)</i> Tissue Banks International Attn: James SaFranko National Processing Center 2597 Kerner Blvd. San Rafael, California 94901  a. PHONE 415-464-6111 EXT _____																	
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																	
		j. Pericardium											X	X	X	X	X	X	X
k. Peripheral Blood Stem Cells <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic																			
l. Sclera											X	X	X	X	X	X	X	TranZgraft, See next page	
m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous																			
<b>7. ENTER CORRECTIONS TO ITEM 6</b> b. PHONE _____		n. Skin										X	X	X	X	X	X	X	TranZgraft ACD, See next page
		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										X	X	X	X	X	X	X	TranZgraft
		q. Umbilical Cord Blood Stem Cells <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 James SaFranko b. E-MAIL jsafranko@tbionline.org c. TITLE VP, Regulatory & Quality and CQO d. DATE 08-DEC-2011		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)

2

FEI: 1000100754

**ADDITIONAL INFORMATION:**

a. Bone - Private label allografts  
Aesculap Implant Systems: CESPAC Bone & PROSPACE Bone  
Alphatec Spine: AlphaGRAFT  
Integra OrthoBiologics & Integra Spine: Allograft Cancellous Bone  
Pinnacle Spine Group: Human Allograft Bone  
Stability Biologics: Human Allograft Bone  
j. Pericardium - Private label allografts  
New World Medical: Human Tissue Allograft (TPH & TPD)  
l. Sclera - Private labe allografts  
New World Medical: Human Tissue Allograft (TSH)  
n. Skin - Private label allografts  
TBI/Tissue Banks International: Fresh Skin, Cryopreserved Skin &  
InteguPly  
Biomet Biologics & Biomet Sports Medicine: DermaSpan ACD  
Stryker/MMI: MemoDerm

**Proprietary Name(s):**