

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) <i>(See reverse side for instructions)</i>	1. REGISTRATION NUMBER (Field Establishment Identifier) FEI: 1000100754	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 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. _____													
4. PHYSICAL LOCATION <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			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			TranZgraft
5. ENTER CORRECTIONS TO ITEM 4													
		g. Heart Valve											
		h. Ligament		X		X	X	X	X	X			TranZgraft
		i. Oocyte <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
6. MAILING ADDRESS OF REPORTING OFFICIAL <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 _____		j. Pericardium		X		X	X	X	X	X			TranZgraft, See next page
		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			TranZgraft, See next page
		m. Semen <input type="checkbox"/> SIP <input type="checkbox"/> Directed <input type="checkbox"/> Anonymous											
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE _____													
		n. Skin		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											
8. U.S. AGENT													
		p. Tendon		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											
a. E-MAIL		r. Vascular Graft											
9. REPORTING OFFICIAL'S SIGNATURE													
		s.											
		t.											
a. TYPED NAME James SaFranko		u.											
b. E-MAIL jsafranko@tbionline.org		v.											
c. TITLE VP, Regulatory & Quality and CQO													
d. DATE 08-DEC-2011													

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):