

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: 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 VALIDATED BY FDA:25-DEC-2014 DISTRICT: San Francisco PRINTED BY FDA:02-FEB-2015								
PART I - ESTABLISHMENT INFORMATION 3. OTHER FDA REGISTRATIONS a. BLOOD FDA 2830 NO. _____ b. DEVICES FDA 2891 NO. _____ c. DRUG FDA 2656 NO. _____		PART II - PRODUCT INFORMATION 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	14. PROPRIETARY NAME(S)
		Establishment Functions										
		Types of HCT / Ps	Recover	Screen	Test	Package	Process	Store	Label	Distribute		
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) TBI San Francisco 880 Harbour Way South Richmond, California 94804 a. PHONE 855-416-0596 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 Additional Information
		b. Cartilage		X		X	X	X	X	X	X	TranZgraft
		c. Cornea		X		X	X	X	X	X	X	VisionGraft
		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
5. ENTER CORRECTIONS TO ITEM 4		g. Heart Valve										
		h. Ligament		X		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 (Include institution name if applicable, number and street, city, state, country, and post office code) TBI/Tissue Banks International Attn: Petar Georgiev 880 Harbour Way South Richmond, California 94804 a. PHONE 510-730-7886 EXT _____		j. Pericardium		X		X	X	X	X	X	X	TranZgraft, See Additional Information
		k. Peripheral Blood Stem <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		l. Sclera		X		X	X	X	X	X	X	
		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	X	X	*** See full text on next page
		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		p. Tendon		X		X	X	X	X	X	X	TranZgraft
		q. Umbilical Cord Blood <input type="checkbox"/> Autologous <input type="checkbox"/> Family Related <input type="checkbox"/> Allogeneic										
		r. Vascular Graft										
9. REPORTING OFFICIAL'S SIGNATURE a. TYPED NAME Petar Georgiev b. E-MAIL pgeorgiev@tbionline.org c. TITLE Manager, Quality Assurance d. DATE 24-DEC-2014		s.										
		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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ADDITIONAL INFORMATION:

a. Bone - Private Label HCT/Ps
Aesculap Implant Systems: CESPAC Bone and PROSPACE Bone
Biomet Spine: Cellentra VCBM
Integra OrthoBiologics & Integra Spine: Allograft Cancellous Bone
Tritium BioSciences, LLC: Allograft Cancellous Bone
Solana Surgical: TenFuse Machined, Sterile Bone Matrix

j. Pericardium - Private Label HCT/Ps
New World Medical: Human Tissue Allograft (TPH & TPD)

n. Skin - Private Label HCT/Ps
Biomet Biologics & Biomet Sports Medicine: DermaSpan ACD
Stryker/MMI: MemoDerm Acellular Dermal Matrix

Proprietary Name(s):
n. Skin TranZgraft ACD

Proprietary Name(s):
n. Skin TranZgraft ACD, See Additional Information