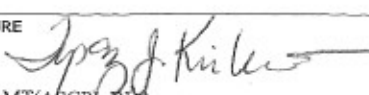


DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE FOOD AND DRUG ADMINISTRATION ESTABLISHMENT REGISTRATION AND LISTING FOR HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/Ps) (See reverse side for instructions)		1. REGISTRATION NUMBER (Field Establishment Identifier)  FEI: 3003415347	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:29-JUN-2011 DISTRICT: Florida PRINTED BY FDA:29-JUN-2011								
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. FEI: 3003415347 c. DRUG FDA 2856 NO. _____		10. ESTABLISHMENT FUNCTIONS AND TYPES OF HCT / Ps																
4. PHYSICAL LOCATION (Include legal name, number and street, city, state, country, and post office code) Bio-Tissue, Inc. 7000 SW 97 Avenue Suite 211 Miami, Florida 33173  a. PHONE 305-412-4430 EXT 214 b. <input type="checkbox"/> SATELLITE RECOVERY ESTABLISHMENT (MANUFACTURING ESTABLISHMENT FEI NO. _____) c. <input type="checkbox"/> TESTING FOR MICRO-ORGANISMS ONLY		Types of HCT / Ps		Establishment Functions							11. HCT/Ps DESCRIBED IN 21 CFR 127.118	12. HCT/Ps REGULATED AS BIOLOGICAL DRUGS	13. HCT/Ps REGULATED AS MEDICAL DEVICES					
5. ENTER CORRECTIONS TO ITEM 4		Recover	Screen	Test	Package	Process	Store	Label	Distribute									
6. MAILING ADDRESS OF REPORTING OFFICIAL (Include institution name if applicable, number and street, city, state, country, and post office code) Bio-Tissue, Inc. Attn: Topaz J. Kirlaw, MT(ASCP), DBA 7000 SW 97 Avenue Suite 211 Miami, Florida 33173  a. PHONE 305-412-4430 EXT 214		a. Bone																
7. ENTER CORRECTIONS TO ITEM 6 b. PHONE		b. Cartilage																
8. U.S. AGENT		c. Cornea																
9. REPORTING OFFICIAL'S SIGNATURE  a. TYPED NAME Topaz J. Kirlaw, MT(ASCP), DBA b. E-MAIL tkirlaw@biotissue.com c. TITLE Executive Vice President d. DATE 28-JUN-2011		d. Dura Mater																
		e. Embryo																
		f. Fascia																
		g. Heart Valve																
		h. Ligament																
		i. Oocyte																
		j. Pericardium																
		k. Peripheral Blood Stem																
		l. Sclera																
		m. Semen																
		n. Skin																
		o. Somatic Cell Therapy Products																
		p. Tendon																
		q. Umbilical Cord Blood																
		r. Vascular Graft																
		s. Amniotic Membrane	X	X		X	X	X	X	X	X	X	X	X	X	X	X	*** See full text on next page
		t. Placenta	X	X		X	X	X	X	X	X	X	X	X	X	X	X	AMNIOPATCH (tissue graft)
		u. Umbilical Cord	X	X			X							X				
		v.																

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**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: 3003415347

**ADDITIONAL INFORMATION:**

**Proprietary Name(s):**

. Amniotic      AMNIOGRAFT, AMNIOGUARD, NEOX 100 &  
Membrane      NEOX 1K (tissue grafts); PROKERA (medical device)